EXPERT REPORT

Analysis of Distributor Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances on behalf of Lake and Trumbull Counties, Ohio

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Prepared by
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I. QUALIFICATIONS AND EXPERIENCE

Statement of Qualifications

- 1999 graduate of Eastern Michigan University with a degree in Public Administration.
- 26 years of law enforcement experience.
- Retired in 2002 as an Executive Lieutenant with the Romulus Police Department.
- Drug Enforcement Administration Diversion Investigator assigned to the Detroit Divisional Office from September 2004 through retirement in June 2017. Diversion Investigators are responsible for several different types of investigations including regulatory investigations, state-action related investigations, pre-registration application investigations, civil investigations, administrative investigations, and criminal investigations. In 2011 Detroit DEA management restructured the responsibilities of the diversion investigators in the Detroit Divisional Office. At that time, Mr. Rafalski's primary responsibility was to conduct administrative, civil, and regulatory investigations of DEA registrants.
- Successfully completed the following DEA training: Basic Diversion Investigator School (2004), Distributor Briefing/Training (2008), Advanced Diversion Investigator School (2009), Comprehensive Regulatory Investigation Training (2010), Diversion Leadership School (2011), Advanced Diversion Investigator School (2015).
- Participated as a DEA Instructor in the design and presentation of the following training programs: Task Force Officers Training and Orientation, Detroit, Michigan (January 2009), Basic Narcotics Training, Macomb Police Academy, Clinton Township, Michigan (April 2009), U.P. Prescription Diversion/Asset Forfeiture Class, Marquette, Michigan (July 2009 and September 2010), and Basic Narcotic Investigator Course, Richmond, Kentucky (May 2010). Prescription Drug Diversion, Gaylord, Michigan (2015)

Awards

- Maintained a performance rating of "Outstanding" from 2005 to 2016.
- Received DEA performance awards from 2009 to 2015 and in 2017.
- Received an award from the Detroit Federal Executive Board in 2013 for exemplary public service to the DEA.
- DEA Administrator's Award for the investigation of the Harvard Drug Group.

- In June of 2013 and September of 2017 he received recognition from the United States Attorney's Office, Eastern District of Michigan for the Harvard Drug Group and Mallinckrodt LLC

Significant Investigations

- **2004 -2008 Investigation of Dr. Leo Ognen**
  - Criminal opioid investigation related to improper prescriptions.
  - Led to the creation of prescribing database utilized in Ohio.
  - Conducted interviews with employees of pharmaceutical companies.
  - Resulted in conviction and incarceration.

- **2006 – 2011 Investigation of Dr. Sohrab Shafinia, D.O.**
  - Criminal opioid investigation of conspiracy to possess controlled substances with intent to distribute.
  - Investigation led to the identification and conviction of an organized prescription drug ring.
  - Extensive reviews of Michigan Automated Prescribing Records (MAPS)
  - Conducted interviews, surveillance, recruiting and utilizing cooperating individuals, as well as undercover activities.
  - Investigation led to the identification and conviction of the responsible pharmacist.

- **2006 – 2008 Investigation of Dr. Louis Cannella, M.D.**
  - Criminal opioid investigation related to improper prescriptions.
  - Extensive reviews of Michigan prescription monitoring program records.
  - Led to the creation of a Wisconsin prescription database.
  - Conducted numerous interviews of witnesses and defendants, surveillance, recruiting and using cooperating individuals, as well as other investigative activities.
  - Resulted in conviction and incarceration.

- **2006 Regulatory Investigation of Walgreens, Perrysburg, Ohio**
  - Unannounced regulatory investigation related to ensuring compliance with regulations and record keeping involving controlled substances.
  - Conducted an accountability audit, record-keeping review, and security investigation.
  - Resulted in the issuance of a Letter of Admonition for inadequate SOMS.

- **2007 Regulatory Investigation of Lake Erie Medical Supply**
  - Regulatory investigation related to repackaging, relabeling and distribution of controlled substances mainly to physicians and medical offices.

- Recommended a distributor briefing at DEA headquarters in November 2008 to reiterate regulatory requirements to registrants.
- Attended the November 2008 distributor briefing presented by other Diversion Investigators.

- **2010 – 2011 Administrative Investigation of The Harvard Drug Group**
  - Conducted a review of ARCOS data to identify any unusual patterns of distribution of oxycodone to Florida pain clinics.
  - Conducted extensive review of company records and policies, controlled substance order forms, DEA Form 222s, and interviews of employees.
  - Conducted review of chargeback system.
  - Investigation led to an Order to Show Cause in June of 2010 for among other things, developing work around as to not trigger SOMS.
  - Investigation concluded with entry of an Administrative Memorandum of Agreement that remained in effect for three years.

- **2010 – 2013 Administrative Investigation of Masters Pharmaceutical**
  - Met with and interviewed employees and initiated an on-site investigation.
  - Served several DEA Administrative subpoenas and obtained 21 customers files to review.
  - Reviewed customer files which contained customer due diligence including but not limited to: questionnaires, on-site investigation reports, written notations, utilization reports, ship to memos, SOMS information, and electronic notations.
  - Investigation concluded with the issuance of an Order to Show Cause.
  - Order to Show Cause resulted in revocation of DEA registration which was affirmed by United States Court of Appeals for the District of Columbia Circuit.

- **2010 – 2017 Administrative Investigation of Mallinckrodt L.L.C.**
  - Administrative investigation begun in response to information related to a chargeback program based on other investigations.
  - Reviewed the chargeback discount program and transactional information involved in the program, which included the purchasers name, address, type and strength of drug, and date of transaction.
  - The investigated chargeback data contained information that allowed Mallinckrodt to see the geographic distribution of their products, the volume and size of purchases.
  - Chargeback data also disclosed some pharmacies and/or practitioners utilizing multiple distributors to purchase the same product in large quantities.
  - Through an administrative subpoena requested documents related to suspicious order system and related policies, related compliance policies,

chargeback data, customer files, internal and external communications to include emails, written correspondence, and notes.

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice on suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the distributor/pharmacy defendants to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.[1] I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken in MDL2804 and other opioid litigation that I have been asked to provide opinions in and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed hundreds of thousands of documents. I have relied upon the defendants' answers to discovery requests as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of $300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is $500.00 per hour. I have not previously provided expert testimony at trial. I have provided expert testimony by deposition in *In re: National Prescription Opiate Litigation*, MDL No. 2804 (Case Track One and Case Track Two) and in the New York State litigation, *In re Opioid Litig.*, Index No. 400000/2017. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

[1] I provide all opinions in this report with a reasonable degree of professional certainty.

II. OPINIONS

Based on my education, background, experience, and review of the documents produced in this matter and provided to me, my opinions, which are more fully set forth throughout this report, are as follows:

1. The Controlled Substance Act (CSA) is designed to provide for a closed delivery system related to the pharmaceutical supply chain. The CSA requires DEA registration for each member of the closed supply chain, known as a registrant. This is due to the dangerous and abusive nature of the controlled substances that flow through the pharmaceutical supply chain.

2. As a member of the closed delivery system each registrant takes on certain statutory and regulatory obligations to ensure the safety and efficiency of the pharmaceutical supply chain. These statutory and regulatory duties have remained the same sense the enactment of the CSA.

3. The pharmaceutical supply chain flows from manufacturer (labeler) to wholesale distributor and then to the end dispenser (pharmacy, hospital, practitioner). This gives the distributors a unique position in the supply chain in that they are the last checkpoint before the controlled substances go to the end dispenser.

4. Under the CSA and the implementing regulations the distributors have two significant obligations that are designed to ensure that these controlled substances do not veer outside of the closed supply chain. These statutory and regulatory obligations come from:

    - 21 U.S.C.A. § 823(b)(1); which requires the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."

    - 21 C.F.R. § 1301.74(b); which require the registrant to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Then the registrant is required to notify the DEA of all identified suspicious orders prior to shipment.

5. Each of these obligations play a vital role in protecting the integrity of the pharmaceutical supply chain. It is up to each registrant to design a system, often referred to as a suspicious order monitoring system (SOMS), that will comply with these regulatory requirements based on the differing type of business models they choose as customers. For example, a wholesale distributor that only services hospitals would need a SOMS different from that for one who services veterinary clinics.

6. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop and implement a SOMS that would ensure the maintenance of effective controls against diversion. While each of them had different systems for which they implemented each of these systems were either faulty in their design or in the manner they were operated.

7. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to develop a comprehensive system to monitor, detect, and report all suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties. This failure is exacerbated as there were significant timeframes when the Defendants would identify suspicious orders and still ship the orders to the respective pharmacies.

8. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to conduct adequate due diligence on suspicious orders of opioids placed by pharmacies in Lake and Trumbull Counties, to determine whether the customer was engaged in diversion;

9. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each distributed opioids to pharmacies in the Lake and Trumbull Counties in disproportionately excessive amounts without adequately documenting justification; and

10. CVS, Walmart, Walgreens, Rite Aid and HBC/Giant Eagle each failed to halt suspicious shipments of opioid orders to pharmacies in Lake and Trumbull Counties they knew, or should have known, were going to be diverted.

III. STANDARDS

A. STATUTORY DUTY.

Each distributor/pharmacy owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA

and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.[2]

The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.[3] Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.[4]

The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain ***illegal***.[5] "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."[6]

Distributors of Schedule II drugs—controlled substances with a "high potential for abuse"[7] – must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[8] The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[9] The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.[10]

Based on my review of all the relevant documents and testimony taken in this case (MDL 2804) it is my opinion to a reasonable degree of professional certainty that the multiple distributors servicing Lake County and Trumbull County failed to maintain effective control against diversion

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[2] *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

[3] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

[4] 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

[5] 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

[6] *United States v. Moore*, 423 U.S. 122, 135 (1975).

[7] 21 U.S.C. §§ 812(b), 812(2)(A)-(C)

[8] 21 U.S.C. § 823(b)(1).

[9] 1970 U.S.C.C.A.N. 4566, 4571-72.

[10] 1970 U.S.C.C.A.N. 4566, 4574.

of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1).

B. REGULATORY DUTY

Each distributor "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[11]

This regulatory duty has been defined to include the following obligations:

> The "***security requirement***" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the ***Reporting Requirement***). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out "potential illegal activity." *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the ***Shipping Requirement***).[12]

The regulatory duty is not difficult to follow and understand. An entity who voluntarily applies to become a registrant must submit an application and undergo a pre-registration investigation. The pre-registration investigation involves a thorough onsite inspection of the registrant's facilities as well as extensive instructions on the applicable regulations and the security requirements that must be followed. While there are numerous requirements related to registration, my opinions focus on the following compliance requirements:

- Maintain effective controls to prevent the diversion of controlled substances into "other than legitimate medical, scientific, and industrial channels";
- "Design and operate" a system to identify suspicious orders; and
- Report suspicious order "when discovered."

C. MDL2804 Discovery Ruling 12

[11] 21 C.F.R. § 1301.74(b) [1971]

[12] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added).

The Court in MDL2804 issued a discovery ruling (Discovery Ruling 12) which outlines the statutory and regulatory duties imposed by federal law upon distributors of controlled substances.[13] The ruling addresses the following legal standards:

> Distributors of opioids are required to "'design and operate a system' to identify 'suspicious orders of controlled substances' and report those orders to DEA (the Reporting Requirement)." *Masters Pharmaceutical*, 861 F.3d 206, 212 (D.C. Cir. 2017) (quoting 21 C.F.R. § 1301.74(b)). Federal regulations explain that "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Thus, an order for opioids received by a distributor from a retail pharmacy may qualify as "suspicious" for any of a number of different reasons.[14]
>
> The simplest example is that a given order for an opioid may be suspicious if it was of "unusual size" – say, an order that pushed a pharmacy's monthly total number of opioid doses to exceed the monthly totals the same pharmacy had ordered in the prior six months. The Order refers below to this algorithm as the "Monthly Total Rule." (*Masters Pharmaceutical* described the "Monthly Total Rule" as follows: an order is suspicious if "that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months." *Id.* at 213.)

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[13] See Discovery Ruling No. 12 regarding Suspicious Order Interrogatory [Doc. 1174].

[14] "Of course, an order may be suspicious for other reasons, even if it doesn't fit the Monthly Total Rule, such as that the pharmacy-customer "submitted more order forms in a 30-day period than it had in any of the prior six calendar months [the 'Order Form Rule'], or if the timing of the order did not comport with the customer's general ordering pattern over those six months [the 'Order Timing Rule']." *Id.* There are many other algorithms a distributor could use to identify opioid orders as suspicious, including: (1) the order for the opioid was placed within 30 days of an earlier suspicious order for the same opioid (the "Consecutive Order Rule"); (2) the order for the opioid was placed within 30 days of an order for the same opioid from a different distributor (the "Multi-Distributor Rule"); (3) the percentage increase in the amount of opioid ordered exceeded a certain threshold (the "Percentage Increase Rule"); or (4) the amount of opioid ordered exceeded by some threshold the amounts ordered by other similar or nearby pharmacies ("the Pharmacy Comparison Rule").

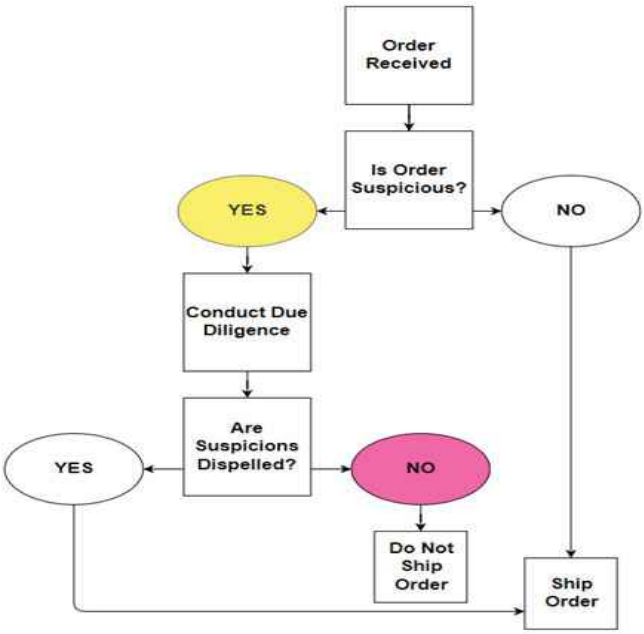
"*See also Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) ("a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy that engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious."); *id.* at *55478 (noting that "suspicion" is a low bar: it "is simply a far lower standard of proof than whether it is 'likely' that the circumstance exists," and "the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.")" Discovery Ruling No. 12, fn 2.

> As noted, once it has identified a suspicious order, a distributor is required to report it to the Drug Enforcement Agency ("DEA"). *See* 21 C.F.R. §1301.74(b) ("The [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [distributor]."). Furthermore, having received a suspicious order, the distributor "must make one of two choices: decline to ship the [suspicious] order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Id.* at 212–13. Of course, a distributor's due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed." *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) (hereinafter, "*Decision and Order*"). Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence." *Masters Pharmaceuticals*, 861 F.3d at 212.[15]

The Order noted the "legal authorities reviewed above leave unclear exactly when an order is deemed suspicious, and thus when a distributor is required to inform the DEA that it received a suspicious order. The following flowchart illustrates the issue."[16]

[15] Discovery Ruling No. 12 [Doc. 1174]. *See also*, *id.*, at n.3 ("The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.")

[16] *See* MDL 2804 Discovery Ruling No. 12, issued December 9, 2018 at page 5 [Doc. 1174].



This flowchart shows how a distributor's Suspicious Order Monitoring System must work and diagrams the process a distributor must undertake when it receives a suspicious order. Notably, there is a "yellow light" (caution) and a "red light" (stop) in the process. When a distributor first identifies an order as suspicious, this is a "yellow light" – it cannot ship the order without doing some investigation. If that investigation does not "dispel all red flags indicative that a customer is engaged in diversion," then the distributor gets a "red light" and must not ship the order. *Masters Pharmaceutical*, 861 F.3d at 222. Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done.

With regard to the Reporting Requirement, it is not entirely clear whether a distributor's obligation to inform the DEA attaches: (1) when the "yellow light" flashes – that is, when the distributor first identifies an order as suspicious; or (2) only after the "red light" flashes – which would mean a distributor does not have to inform the DEA it received a suspicious order if investigation shows the order was legitimate, after all. Indeed, the authorities cited above provide support for each approach, as shown by the following quotations.

"Red Light"

- "[I]f, ***even after investigating the order***, there is any remaining basis to suspect that a customer is engaged in diversion; the order must be deemed suspicious and the Agency must be informed. *Decision and Order*, 80 Fed. Reg. at *55478.

- "DEA regulations expressly provide that deviations in size, frequency, or pattern are the sort of indicia that give rise to a suspicion and, ***unless the suspicion is dispelled***, the obligation to report. *Masters Pharmaceuticals*, 861 F.3d at 215 (citing *Decision and Order*, 80 Fed. Reg. at *55,479; and 21 C.F.R. §1301.74(b)).

"Yellow Light"

- "***Once a distributor has reported a suspicious order***, it must make one of two choices: decline to ship the order or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Masters Pharmaceutical*, 861 F.3d at 212–13.[17]

In other words, the Court determined it is unclear whether an order is "suspicious" (and so must be reported to the DEA) as soon as a distributor's SOMS flags it as suspicious, or only after due diligence fails to dispel any suspicion.[18] In any event, it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless they conduct "due diligence" that determines those orders are not likely to be diverted. Further, distributors are required to report suspicious orders to the DEA upon discovery.

D. ARCOS/DADS

The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)[19] system is used to track and report the transfer of

[17] Discovery Ruling No. 1.

[18] The Court subsequently confirmed the accuracy of Discovery Ruling No. 12's explanation of registrants' duties under the Controlled Substance Act in its Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act [Doc. 2483].

[19] "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the

pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970[20] and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.[21]

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.[22]

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, among other things, the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

The ARCOS/DADS system uniquely has access to ***all*** of the data submitted by each DEA registrant from the across the country.[23] These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining

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United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, https://www.deadiversion.usdoj.gov/arcos/#background (last visited April 16, 2021)

[20] 21 U.S.C. 826(d).

[21] 69 FR 51104-02.

[22] *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

[23] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

quota, distribution trends, internal audits, inspection, investigations and other analyses.[24] Additionally, the DEA provides internet access to summary data from this system.

The DOJ/DEA disclosed the national ARCOS database to the Plaintiffs' Executive Committee (2006-2014) and additional transactional data was independently disclosed by some of the defendants. Both sets of data were then uploaded to a database managed by Craig J. McCann, PhD, CF, of Securities Litigation and Consulting Group, Inc. ("SLCG") (retained as an expert by the PEC). I have relied upon data derived from and provided by SLCG in the formulating of specific requests.

The ARCOS data, defendant transactional data, and the SLCG reports generated therefrom are consistent with the types of data, facts, information, and reports I would typically rely on in conducting the analysis and reaching the opinions contained herein. I am very familiar with the ARCOS data and defendant transactional data and have experience analyzing the data and reports generated therefrom. I have reviewed SLCG's methods and reports and they are consistent with my understanding, based on my experience, of how the data should be analyzed.

E. DEA DIVERSION INVESTIGATOR'S MANUAL.

The DEA published a manual which provides further guidance related to the statutory and regulatory duties of registrants. Portions of the manual have previously been publicly available and accurately set forth the charge for DEA investigators as follows:

> Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. ***The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.*** An investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.[25]

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[24] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html (last visited April 16, 2021).

[25] *See* DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176914 at 01176957) ; *see also* DEA Diversion Manual (1990) (CAH_PRIORPROD_DEA_01176247 at 01176301); DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317 at 00953396, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("By its very nature, an order is a request to purchase controlled substances and has not yet been filled.

Importantly, the DEA does not approve or disapprove supplier shipments of controlled substances. The responsibility for making the decision to ship rests with the supplier.[26]

F. DEA DISTRIBUTOR INITIATIVE BRIEFINGS.

In August 2005, the DEA designed and implemented the DEA Distributor Initiative. The initiative was in response to the growing number of rogue Internet pharmacies illegally dispensing controlled substances and their pattern of purchasing extremely large amounts of a limited type of controlled substances from distributors. This program consisted of an individual meeting between the DEA and distributors to re-iterate to DEA registrants their responsibilities under the Controlled Substances Act and Code of Federal Regulations and to discuss current trends and methods of diversion.

In February 2014, at a conference in North Carolina, DEA Deputy Assistant Administrator Joseph T. Rannazzisi reported that the DEA had conducted distributor briefings to 81 registrants that had a total of 233 registered locations. The DEA has produced in discovery summaries of some of these meetings as follows:

- Memorandum, Meeting with Cardinal Health, Inc. Concerning Internet Pharmacies on August 22, 2005;[27]
- Memorandum, Conference Call with. Mr. John. Gilbert of McKesson Corp. on November 28, 2005;[28]
- Memorandum, Meeting Between Office of Diversion Control (OD) and McKesson Corp. on January 3, 2006;[29]
- Memorandum, Internet Presentation; with AmerisourceBergen on August 10, 2005;[30] and
- Memorandum, Distributor Initiative Briefing with AmerisourceBergen Drug on May 16, 2017.[31]

Reporting a filled order is potentially allowing controlled substances to be diverted. Therefore, suspicious orders will not be filled.")

[26] See DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176247); see also DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("DEA field offices will not approve or disapprove a registrant's shipment of controlled substances, nor their procedures for detecting suspicious orders. The responsibility for detecting suspicious orders and making the decision to ship rests solely with the registrant.")

[27] US-DEA-00000352.

[28] US-DEA-00000369.

[29] US-DEA-00000371.

[30] US-DEA-00000147.

[31] US-DEA-00000144

At these briefings DEA personnel would reiterate the registrant's requirement to maintain effective controls to prevent diversion as required in U.S.C. 21 § 843(e) and 21 C.F.R. § 1301.71(a). During these meetings the DEA specifically focused on discussing 21 C.F.R. § 1301.74(b) which states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." DEA also advised the registrant at these meetings that DEA cannot tell a distributor if an order is legitimate or not.[32] The distributor has the responsibility to determine which orders are suspicious and once identified the distributor should report those orders to DEA and should not distribute suspicious orders.[33] Further, it was reiterated that a distributor was advised prior to shipping any order that had been determined to be suspicious, the distributor should conduct a due diligence investigation to ensure the controlled substances in the order are not likely to be diverted and document their due diligence actions.[34] Failure to do so could result in action against their DEA registration.

G. SEPTEMBER 2006 DEA GUIDANCE LETTER

In September 2006, in response to the nationwide growing health problems involving diversion of controlled substances, DEA Deputy Assistant Administrator Joseph T. Rannazzisi forwarded a letter to all DEA registered distributors and manufacturers.[35] The purpose of the letter was to reiterate the legal duties of distributors as DEA registrants and provide some examples of activities that may be indicative of diversion.

Mr. Rannazzisi's letter referenced 21 U.S.C. 823(e) that restated the requirement that distributors and manufacturers have a legal requirement to maintain effective controls against diversion. Mr. Rannazzisi's letter further cited DEA Regulation 21 C.F.R. 1301.74(b) which states the requirement for a registrant to design and operate a system to disclose suspicious orders of controlled substances and to report suspicious orders to the D.E.A. when discovered. The system should be capable of identifying a suspicious order based on size, pattern and frequency and of reporting that order to DEA. Contained in the written notification was a list of circumstances that may be indicative of diversion, which included the following:

a. Ordering excessive quantities of a limited variety of controlled substances

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[32] US-DEA-00000352, 00000360.

[33] *Id.*

[34] *See also Novelty Distributors, Inc.,* 73 Fed. Reg. 52,689, 52,669 (Drug Enf't Admin. September 3, 2008) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.")

[35] *See* CAH_MDL_PRIORPROD_DEA07_00837645; Prevoznik 4/18/19 Depo., 763:7-19.

b. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.

c. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.

d. Ordering the same controlled substances from multiple distributors.

The written communication also listed some guidance for a distributor by providing some possible inquiries of a customer's business activity that could be indicative of diversion. Mr. Rannazzisi further stated and reiterated:

> The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):
>
> > The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
>
> It bears emphasis that the foregoing ***reporting requirement is in addition to, and not in lieu of the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.***
>
> This, in addition to reporting all suspicious orders, ***a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels***. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.[36]

H. JUNE 2007 SOUTHWOOD PHARMACEUTICALS, INC. DISTRIBUTOR CASE

DEA Deputy Administrator Michele M. Leonhart issued an Order on June 22, 2007[37], detailing the revocation of DEA registration for Southwood Pharmaceuticals, Inc ("Southwood"). The Order further denied any pending applications for renewal or modification of registration because of the imminent danger to the public health or safety.

The language contained in this Order clearly re-iterated the requirement for a distributor to have a suspicious order monitoring program. The Order states the following, "a registrant must

[36] *See id.* (emphasis added).

[37] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007).

'design and operate a system to disclose to the registrant suspicious orders of controlled substances'"; suspicious orders must be reported to the local Field Division Office upon discovery by the registrant.[38] Under the regulation, suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.''

This Order also contains a description of the conduct of Southwood causing the revocation of their DEA registration as described in the Order to Show Cause and Immediate Suspension Order of Registration (OTSC/ISO) issued on November 30, 2006. The OTSC/ISO detailed that Southwood distributed controlled substances to customers they knew or should have known were diverting controlled substances. The OTSC/ISO stated Southwood repeatedly supplied excessive quantities of hydrocodone to fifteen pharmacies that were orders of unusual size and frequency as well as substantially deviating from the normal pattern. The OTSC/ISO further stated Southwood never reported any of the orders as suspicious to the DEA.

The OTSC/ISO also stated that Michael Mapes of the DEA conducted a meeting with Southwood by conference call on July 17, 2006. The content of the meeting described in the OTSC/ISO is consistent with the DEA Distributor Program being conducted by the DEA and described in this timeline. During this meeting Mr. Mapes discussed the purchasing activities of several pharmacies who were customers of Southwood. During this meeting Mr. Mapes also provided Southwood with a description of the illegal conduct of Internet pharmacies and described factors to consider when assessing customers for potential diversion. These factors included the size and frequency of order, range of product order, and the percentage of control substances ordered when compared to non-controlled substances. Mr. Mapes further discussed the factors that are required to ensure a prescription is legally prescribed by a physician.

The following statement is contained in the OTSC/ISO, "a pattern of drugs being distributed to pharmacies [which] are diverting controlled substances demonstrates a lack of effective controls against diversion by the distributor" and could lead to the revocation of the distributor's registration." Mr. Mapes further stated, "… any distributor who was selling controlled substances that are being dispensed outside the course of professional practice must stop that distribution immediately."[39]

The OTSC/ISO stated Mr. Mapes discussed with Southwood representatives whether it could ship an order which it had reported as suspicious. Mr. Mapes advised Southwood representatives if they reported a suspicious order to the DEA they still needed to make the decision as to whether to ship the order. The OTSC/ISO further detailed that Southwood representatives asked Mr. Mapes whether they should stop shipping controlled substances to the internet pharmacies and Mr. Mapes replied the DEA cannot tell a distributor whether a particular order is legitimate, and that the decision of whether to ship was "a business decision," but Southwood had an obligation to ensure that the controlled substance being distributed were used for legitimate medical purposes.

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[38] 21 CFR 1301.74(b).

[39] *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487, 36,492 (Drug Enf't Admin. July 3, 2007).

I. DECEMBER 2007 DEA GUIDANCE LETTER

In December 2007, DEA Deputy Assistant Administrator for the Office of Diversion Control, Joseph T. Rannazzisi issued a second letter to all DEA registered distributors and manufacturers restating much of the information contained in the previous letter.[40]

This letter was focused on reiterating the responsibilities of manufacturers and distributors to inform DEA of suspicious orders as required by 21 CFR 1301.74(b).

The letter reiterated that 21 CFR 1301.74(b) requires a manufacturer or distributor to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The letter further notified registrants that it is the sole responsibility of registrants to design and operate the system. The letter advised registrants of the following, "Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for report suspicious orders, should no longer be taken to mean that DEA approves a specific system."[41]

The letter also notifies that filing a monthly report of transactions to the DEA, often referred to as excessive purchase reports, does not meet the regulatory requirement to report suspicious orders.

The letter also reiterated the following requirements:

1. 21 CFR 1301.74(b) requires DEA registrants inform the DEA of suspicious orders when discovered by the registrant.
2. DEA registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine if the controlled substances are likely to be diverted.
3. The regulation states suspicious orders include orders of an unusual size, deviating substantially from a normal pattern, and orders of an unusual frequency. The criteria are disjunctive and are not all inclusive.
4. DEA registrants who routinely report suspicious orders, yet fill these orders without first determining whether the orders are not being diverted may be failing to maintain effective controls against diversion that may result in possible action against their DEA registration.

J. DEA ADMINISTRATIVE ACTIONS

Distributors and manufacturers in this industry regularly monitor DEA administrative actions involving maintenance of effective controls against diversion and failure to identify and/or report suspicious orders. There are many different types of sources that make the details of DEA administrative action available for the industry to review. The type of information available can

[40] CAH_MDL_PRIORPROD_DEA07_00092296; Prevoznik 4/18/19 Depo., 765:14-766:6.

[41] *Id*.

be a very in-depth article or a publication as simple as a press release. Two examples of in-depth sources of information are the information published in the Federal Register involving DEA cases against Masters Pharmaceutical Inc. and Southwood Pharmaceuticals Inc.

The DEA posts administrative case information on the Internet on their website at www.deadiversion.usdoj.gov. The DEA and Department of Justice also normally issue press releases on administrative actions that subsequently generate media coverage and reviews by law firms. Further, trade organizations like the Healthcare Distribution Alliance (HDA) typically publish articles regarding DEA administrative actions for review by their members. Typically, when a DEA administrative action occurs, there are several law firms that closely follow the industry and they post articles on their websites that describe the action and offer opinions of future impact to the industry.

Listed below are some of the significant administrative action against distributors and manufacturers for failing to maintain effective controls against diversion and for failing to identify and/or reports suspicious orders:

1. April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency.[42]

2. June 22, 2007, the DEA revoked the Registration of Southwood Pharmaceuticals, Inc. 72 Fed. Reg. 36,487 (Department of Justice; Southwood Pharmaceuticals, Inc.; Revocation of Suspension (July 2, 2007)) on Tuesday, July 3, 2007July 3, 2007, Department of Justice, Drug Enforcement Administration article in the Federal Register, titled, Southwood Pharmaceuticals, Inc.; Revocation of Registration.[43]

3. November 29, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center which suspended their DEA registration for failure to maintain effective controls against diversion of hydrocodone.[44]

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[42] AmerisourceBergen Corporation, *AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of its Orlando Distribution Center's Suspended License to Distribute Controlled Substances*, June 22, 2007, available at https://investor.amerisourcebergen.com/news/news-details/2007/AmerisourceBergen-Signs-Agreement-with-DEA-Leading-to-Reinstatement-of-Its-Orlando-Distribution-Centers-Suspended-License-to-Distribute-Controlled-Substances/default.aspx (last visited April 16, 2021).

[43] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007)(*also available at* https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm (last visited April 16, 2021)).

[44] Cardinal Health, Press Release, *Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility*, November 29, 2007, available at

4. December 7, 2007, DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[45]

5. December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[46]

6. January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone. Cardinal agreed to suspend shipping any controlled substances from the location pending a resolution with the DEA.[47]

7. May 2, 2008, McKesson Corporation agreed to pay a $13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.[48]

8. September 30, 2008, Cardinal Health agreed to pay a $34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances.[49]

(Source: https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx (last visited April 16, 2021).

[45] Cardinal Health, Press Release, *Cardinal Health to Cease Distribution of Controlled Substances from Florida Facility,* December 7, 2007, available at https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-to-Cease-Distribution-of-Controlled-Substances-from-Florida-Facility/default.aspx (last visited April 16, 2021).

[46] CAH_MDL_PRIORPROD_DEA12_00013049.

[47] CAH_MDL_PRIORPROD_HOUSE_0004009.

[48] Settlement and Release Agreement and Administrative Memorandum of Agreement, entered into May 2, 2008, between DEA and McKesson Corporation, available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf (last visited April 16, 2021).

[49] United States Attorney's Office. (October 2, 2008) *Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* [Press

9. [redacted][50]

10. April 21, 2009, Settlement and Release Agreement and Administrative Memorandum of Agreement between DOJ/DEA and Masters Pharmaceutical Inc.[51]

11. June 15, 2010, Order to Show Cause – Immediate Suspension Order served to The Harvard Drug Group, Livonia, MI.[52]

12. June 10, 2010, DEA suspended Sunrise Wholesale, Inc. from selling controlled substances for supplying excessive amounts of oxycodone to "pill mills."[53]

13. October 13, 2010, settlement was reached between the DEA and CVS Pharmacy, Inc. resolving the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy distribution center in Southern California. CVS paid a penalty of $75,000,000.00 and forfeited $2.6 million in profits for a total payment of $77.6 million.[54]

Release]. Available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html (last visited April 16, 2021).

[50] [redacted]

[51] Settlement and Release Agreement and Administrative Memorandum of Agreement between DEA and Masters Pharmaceutical, Inc. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Masters%20Pharmaceutical%20-%202009.pdf (last visited April 16, 2021).

[52] Administrative Memorandum of Agreement between DEA and The Harvard Drug Group, LLC dated March 28, 2011. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Harvard%20Drug%20Group%20-%202011.pdf (last visited April 16, 2021).

[53] LaMendola, Bob. "DEA accuses Sunrise company of supplying painkillers to 'pill mills.'" Sun-Sentinel. June 22, 2010. Available at https://www.sun-sentinel.com/business/fl-xpm-2010-06-22-fl-drug-wholesaler-stopped-20100621-story.html (last visited April 16, 2021).

[54] United States Attorney's Office. (October 14, 2010) *CVS Admits Illegally Selling Pseudoephedrine to Criminals who made Methamphetamine, Agrees to Pay $77.6 Million to Resolve Government*

14. April 18, 2011, Harvard Drug Group agreed to pay $8,000,000 in civil penalties as part of settlement with DEA related to allegations that Harvard failed to have in place an effective system for identifying suspicious orders of controlled substances, violating the Controlled Substances Act.[55]

15. June 10, 2011, Order to Show Cause and Immediate Suspension Order served on Keysource Medical Inc. Keysource Medical distributed 48 million doses of oxycodone products to Florida Pharmacies.[56]

16. July 6, 2011, Order Denying Plaintiff's (Keysource Medical) Motion for Temporary Restraining Order and for Preliminary Injunction.[57]

17. February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone.[58]

18. March 7, 2012, Memorandum of Opinion [Doc. 32] from the United States District Court for the District of Columbia, *Cardinal Health, Inc., vs. Eric H. Holder, Jr.*, Civil Action No. 12-185 (RBW), denying Cardinal's challenge of the DEA's Order to Show Cause and Immediate Suspension of Registration of Cardinal's Lakeland Distribution Center.[59]

19. April 5, 2012, A United States Attorney Office press release stated Keysource Medical agreed to pay a $320,000 fine for failing to guard against diversion of controlled

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Investigation [Press Release]. Available at https://www.justice.gov/archive/usao/cac/Pressroom/pr2010/148.html (last visited April 16, 2021).

[55] United States Drug Enforcement Administration. (April 18, 2011) *Michigan Based Pharmaceutical Wholesaler Harvard Drug Group to Pay $8,000,000 in Settlement* [Press Release]. Available at https://www.dea.gov/press-releases/2011/04/18/michigan-based-pharmaceutical-wholesaler-harvard-drug-group-pay-us (last viewed on April 16, 2021).

[56] United States Drug Enforcement Administration. (June 10, 2011) *Cincinnati Pharmaceutical Supplier's DEA License Suspended* [Press Release]. Available at https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended (last visited April 16, 2021).

[57] *Keysource Medical, Inc., v. Attorney General of the United States, et al.*, No. 1:2011cv00393, *Order Denying Plaintiff's Motion for Temporary Restraining Order and for Preliminary Injunction* [Doc. 22], available at https://law.justia.com/cases/federal/district-courts/ohio/ohsdce/1:2011cv00393/147299/22/ (last visited April 16, 2021).

[58] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[59] Copy of Order available at https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf (last visited April 16, 2021).

substances. and states Keysource Medical agreed to voluntarily surrender their DEA registration in September 2011.[60]

20. May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA was inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years.[61]

21. March 28, 2013, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc and Oklahoma CVS Pharmacy, L.L.C., to resolve claims that CVS violated the CSA by: (1) filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS dispensing records including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions. CVS paid a fine of $11,000,000.00.[62]

22. In July, 2013, the DEA initiated a regulatory investigation at CVS Indiana. After the investigation and after the DEA had informally indicated its displeasure with what it found at CVS, Mark NiCastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. In the correspondence, Mr. NiCastro attempted to explain to the DEA why the CVS Indiana distribution center had never reported a suspicious order and he wrote:

> "In your recent email, you asked for information concerning CVS store orders that have been stopped outside of Indiana. Across the chain, the CVS SOM process has stopped and cancelled orders. I have attached the dates and the offices to which we reported these orders. As we discussed during the DEA audit and during our recent phone call, it is important to remember that CVS is shipping only to its own stores, and there are additional due diligence processes in our pharmacy operations group which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores. This is a primary contributor to the limited

[60] United States District Attorney's Office, Southern District of Ohio. (April 5, 2012) *Cincinnati Pharmaceutical Distributor to Pay $320,000 for Failing to Guard Against Diversion of Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/ohs/news/04-05-12.html (last visited April 16, 2021).

[61] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[62] CVS-MDLT1-000060822 – 000060829.

number of suspicious orders identified through our distributor SOM process."[63]

23. July 17, 2013, Walgreens agreed to pay $80 Million in civil penalties related to allegations that Walgreens was filling numerous prescriptions that Walgreens employees knew, or should have known, were not issued for a legitimate medical purpose.[64]

24. June 19, 2014, in *Masters Pharmaceutical, Inc.* the Administrative Law Judge issued a Recommended Decision in regards to the Order to Show Cause Hearing that occurred on February 24 through 28 and March 3 through 4, 2014. [65]

25. September 2, 2014, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement resolved claims against CVS for filling from April 1, 2012 to July 31, 2012, 153 prescriptions at eight different pharmacies, written by Dr. Pedro Garcia during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a $1,912,500 fine.[66]

26. May 12, 2015, a settlement was reached among the United States and the DEA and CVS Health and all of its subsidiaries and affiliates. The Settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64." The Settlement also covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances into other than21 U.S.C. §823(e)" and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of $22,000,000.00.[67]

27. On July 24, 2015, a Settlement was reached among the United States and the DEA and CVS Health to resolves claims that from May 1, 2013 through July 30, 2014, CVS failed to keep complete and accurate records of Schedule II controlled substances at a CVS store in Massachusetts in violation of 21 U.S.C. § 827(a)(3) and 21 C.F.R. §§ 1304.11(e)(3)(i),

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[63] *See* NiCastro Depo. at 204-207; Ex. 42.

[64] United States Attorney's Office, Eastern District of New York. (July 17, 2013) *Eastern District U.S. Attorney's Office Participates in Record Settlement: Walgreens Agrees to Pay $80 Million in Civil Penalties Under the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-edny/pr/eastern-district-us-attorney-s-office-participates-record-settlement-walgreens-agrees (last visited April 16, 2021).

[65] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

[66] CVS-MDLT1-00060907 – 000060914.

[67] CVS-MDLT1-000060796 – 000060804.

1304.21, and 1304.22; and that CVS failed to report a March 14, 2014 robbery to the DEA within one business day in violation 21 C.F.R. § 1301.76(b). CVS paid a $50,000 fine.[68]

28. On August 7, 2015, a Settlement was reached among the United States and the DEA and CVS Health. The Settlement resolved claims that between March 3, 2010 and August, 2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA number (knew or should have known in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a $450,000 fine.[69]

29. September 8, 2015, Masters Pharmaceutical – DEA Acting Administrator Chuck Rosenberg issued a Final Order revoking the DEA registration of Master Pharmaceutical Inc.[70]

30. On December 18, 2015, a Settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement was the result of a DEA Inspection that was performed after CVS reported the theft of over 40,000 dosages of controlled substances by two former employees from a Texas CVS pharmacy. The inspection that was started due to theft demonstrated that CVS again failed its CSA obligations. CVS paid a fine of $345,000.00.[71]

31. On December 31, 2015, the DEA issued a letter of admonishment for violations in distributing HCPs at the CVS Indiana distribution center. This DEA finding was the result of the July 2013 investigation. Before the admonishment, Agent Gillen of the DEA sent an email to Mr. Nicastro outlining that CVS Store No. 6880 ordered 1,888,600 dosage units of hydrocodone between January 1, 2012 and October of 2013. The pharmacy is located in Vincennes, IN with a population of approximately 18,000 people. Additionally, he indicated that Store No. 6757 ordered 2,012,400 of hydrocodone tablets for Columbus, IN, which has a population of 45,000. Agent Gillen then writes: "Both stores have purchased a large quantity of Hydrocodone given their population."[72]

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[68] CVS-MDLT1-000099702 –000099704.

[69] CVS-MDLT1-000060847 – 000060855.

[70] *Masters Pharm., Inc*., 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

[71] CVS-MDLT1-00060915-00060921.

[72] *See* CVS-MDLT1-00008014 – 00008015; CVS-MDLT1- 000076135.

32. On February 12, 2016, a Settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. In the Settlement, CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA…" CVS paid a fine of $8,000,000.00.[73]

33. June 30, 2016, CVS agreed to pay $3.5 Million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.[74]

34. October 20, 2016, a Settlement was reached among the United States and CVS Pharmacy, Inc. The Settlement resolved claims from an investigation that the DEA began in January 2016. The DEA investigated two CVS stores in Connecticut. Although the offending conduct occurred after CVS quit distributing HCPs, it is indicative of the overall pattern and practice of CVS. The Settlement resolves claims that CVS failed to keep paper Schedule III-V prescriptions either in a separate prescription file or readily retrievable from other prescription records, which allegedly violated 21 U.S.C. 827(b)(2)(A) and (B) and 21 C.F.R. 1304.04(h)(4) and failed to keep Schedule III-V purchase invoices on at least 31 occasions in separate or in a readily retrievable manner from all other records of the pharmacy, which allegedly violated 21 U.S.C. 827(b)(2)(A) AND (b) AND 21 C.F.R. 1304.04(h)(3). CVS paid a $600,000 fine.[75]

35. December 22, 2016, Consent Order entered into between the United States and Kinray, LLC, a subsidiary of Cardinal Health.[76]

36. December 23, 2016, Cardinal Health agreed to pay a $34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligation under the CSA in Florida, Maryland, New York, and Washington.[77]

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[73] CVS-MDLT1-000060805-00060811.

[74] United States District Attorney's Office, District of Massachusetts. (June 30, 2016) *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions* [Press Release]. Available at https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions (last visited April 16, 2021).

[75] CVS-MDLT1 000060830 – 000060838.

[76] *United States of America v. Kinray, LLC*, Case #16 Civ. 8767-RA. Available at https://www.justice.gov/usao-sdny/press-release/file/920806/download (last visited April 16, 2021).

[77] United States Attorney's Office, Middle District of Florida. (December 23, 2016) *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under (last visited April 16, 2021).

37. January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.[78]

38. January 18, 2017, Walgreens agreed to pay $200,000 following an investigation by the Massachusetts Attorney General's Office, which found that Walgreens failed to track the opioid use of high-risk patients in the state's Medicaid program.[79]

39. [redacted][80]

40. June 30, 2017, the United States Court of Appeals for the District of Columbia Circuit published an opinion denying Masters Pharmaceutical's petition of review and upholding the Final Order.[81]

41. July 5, 2017, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement was the result of an investigation began by the DEA as a result of "an increase in the number of thefts and explained losses of Hydrocodone…" at numerous Eastern District of California CVS retail stores. The Settlement resolved claims for the following misconduct: 1) failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances (*see* 21 C.F.R. §1301.71(a)) and failure to notify DEA of certain thefts or significant losses of controlled substances within one business day of the discovery (*see* 21 C.F.R. §1301.74(c)); 2) failure to maintain schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to

[78] United States Department of Justice. (January 17, 2017) *McKesson Agrees to Pay record $150 Million settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* [Press Release]. Available at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (last visited April 16, 2021).

[79] Associated Press, "Walgreens to pay $200k, change opioid procedures," The Washington Times, January 19, 2017, available at https://www.washingtontimes.com/news/2017/jan/19/walgreens-to-pay-200k-change-opioid-procedures/) (last visited April 16, 2021).

[80] [redacted]

[81] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms (21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their recordkeeping obligations, but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of $5,000,000.00.[82]

42. July 7, 2017, Department of Justice/DEA and Mallinckrodt entered into a Memorandum of Agreement to resolve allegations that if failed to maintain effective controls to prevent diversion and to detect and report suspicious orders.[83]

43. [redacted][4]

44. June 15, 2018, a Settlement was reached among the United States and the DEA and CVS Health. The Settlement resolved claims that between February, 2013 and January, 2015, CVS failed to report to the DEA in writing, within one business day of discovery, thefts or significant losses of controlled substances, including hydrocodone, from certain Long Island CVS Pharmacy retail stores, as required by 21 C.F.R. §1301.76(b). CVS agreed to pay a $1,500,000.00 fine. (CVS-MDLT1-000060839 – 000060846).

45. July 29, 2018, a Settlement was reached the among the United States and the DEA and CVS Pharmacy, Inc., to resolve claims related to a November 2013 inspection of a CVS Pharmacy in Calera, Alabama. The Settlement resolved claims that CVS violated the CSA, as a result of violations of : (1) 21 C.F.R. 1305.13(c) (requirement to record the amount received and/or the date received on DEA 222 forms); (2) 21 C.F.R. 1304.21(a) (requirement to maintain complete and accurate records); and (3) 21 C.F.R. 1304.21(a) and/or (d) (requirement to document the number of packages received or the date package received on Schedule III through V purchase invoices). CVS agreed to pay a $1,000,000 fine.[85]

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[82] CVS-MDLT1 000060856-000060871.

[83] Administrative Memorandum of Agreement between DEA and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, dated July 7, 2017. Available at https://www.justice.gov/usao-edmi/press-release/file/986026/download (last visited April 16, 2021).

[84] [redacted]

[85] CVS-MDLT1-000060812 –000060821.

46. August 21, 2018, CVS agreed to pay $1 Million to settle allegations that CVS stores in Alabama failed to keep adequate records in violation of the Controlled Substances Act.[86]

47. [redacted][87]

K. INDUSTRY GUIDELINES - HEALTHCARE DISTRIBUTION ALLIANCE

A large number of drug distributors and manufacturers are members of The Healthcare Distribution Alliance (HDA), a trade organization that provides industry information, provide guidance on best practices, industry standards, regulation/legal changes, and other related services.

A review of the website for The Healthcare Distribution Alliance (HDA) provided the following history of the organization.[88] The Western Wholesale Druggists' Association (WWDA) was formed on March 15, 1876 and consisted of 95 wholesale druggists. In 1882 the WWDA became the National Wholesale Druggists Association (NWDA) that was representing distribution companies as an advocate in the distribution industry.

In 2000 the NWDA organization was renamed Healthcare Distribution Management Association (HDMA). The website stated the organization changed reflected the "Association's vision of a progressively more efficient and effective distribution system." In 2016 the HDMA changed names to the Healthcare Distribution Alliance (HDA). The website states the following, "Now headquartered in Arlington, Virginia, HDA represents 36 distribution companies — national, regional and specialty — as well as more than 130 manufacturer and more than 50 service provider/international members, respectively. These members serve more than 200,000 licensed healthcare providers, delivering over 15 million lifesaving products to these outlets every day. But just as in 1876, HDA's mission has remained the same, which is to protect patient safety and access to medicines through safe and efficient distribution; advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and, create and exchange industry knowledge and best practices."

NWDA 1984 Suspicious Order Monitoring Policy

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[86] United States Attorney's Office, Northern District of Alabama. (August 21, 2018) *CVS Pharmacy Pays $1 Million Penalty in Settlement with DOJ for Violations of the Controlled Substances* [Press Release]. Available at https://www.justice.gov/usao-ndal/pr/cvs-pharmacy-pays-1-million-penalty-settlement-doj-violations-controlled-substances-act (last visited April 16, 2021)

[87] [redacted]

[88] *See* https://www.hda.org/ (last viewed April 16, 2021).

A review of Cardinal Health discovery material revealed a thirty-eight page document from 1984 by NWDA which was a draft outline of a suspicious order monitoring system. The documents can be found in the Cardinal Health discovery material in a group of documents that begin with a cover page containing, "NWDA Suspicious Order Monitoring System" with this stamped information, "Received Jun 21 1993 by Folsom." [89]

The first seven pages of the document describes some of the elements of a suspicious order system. These seven pages do not contain a date indicating when the system was designed. There are two DEA letters in the documents that do identify a date which are letters from the DEA. These DEA letters provide comment and guidance to NWDA in regards to the suspicious order system. The first DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA) and signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA). The letter contained a stamped date of April 27, 1984, which details a meeting between the two on April 13, 1984. This letter stated the DEA reviewed a draft form of the suspicious order monitoring system. This DEA letter contained the following comment:

> The NWDA's draft format for a suspicious order monitoring system provides as excellent framework for distributor registrants to "…design and operate a system to disclose to the registrant suspicious orders of controlled substances." (21 CFR 1301.74(b).) However, I am compelled to note, as I have in our previous discussions, that any automated data compliance processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler. As previously discussed, an after-the-fact computer printout of the sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered. I am enclosing a copy of your draft with my pen-and-ink changes."[90]

The second DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA), signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA) that was stamped with a date of May 14, 1984, which appeared to be a follow-up communication from the April 27, 1984 letter. This letter details that there was a NWDA meeting that was attended by DEA employee David Walkup. This DEA letter contained the following comment:

> I want to assure you that DEA fully supports NWDA's effort to introduce a uniform reporting system among its members. This system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b). However, I want to make it clear that the submission of a monthly printout of after-the-fact sales will not relieve a

[89] The group of documents described in this section can be found in the Cardinal Health discovery material with a Bates stamp range of CAH_MDL2804_01465723 to CAH_MDL2804_01465761.

[90] CAH_MDL2804_01465723, 01465732.

> registrant from the responsibility of reporting excessive or suspicious orders. DEA has interpreted "orders" to mean prior to a shipment.[91]

The background section of the system details it was created in co-operation with the DEA. Further, the document states that the DEA may be providing some variances and limits that would be incorporated into the suspicious order system.

On page 7 of the suspicious order system document is "Section IX" that contains the following statement: "Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of report these excessive or suspicious orders. DEA has interpreted "orders" to mean prior to a shipment." This statement along with the letter from DEA is an important communication that identifies the DEA was requiring the suspicious order system to identify single orders of controlled substances that must report immediately prior to being shipped.

While the Association was still called NWDA, an updated version of the Controlled Substances Manual was produced.[92]The section addressing "Suspicious Orders – Controlled Substances" includes the instruction:

> Distributors should establish written criteria of what constitutes a suspicious order. DEA leaves it to the distributor to make this determination. The key for the distributor is to establish reasonable criteria based upon customer purchasing patterns and then to adhere to them in monitoring orders.[93]

After addressing both computerized and manual monitoring systems, the NWDA Manual includes the following italicized language:

> *It is DEA's position that an after-the-fact monitoring program as previously described(whether computer or manual) does not relieve the distributor of responsibility for policing individual orders that appear excessive. In these situations, DEA should be notified before the order is shipped and a copy of all such orders should be maintained in the distributor's suspicious orders file with a notation reflecting the date and person contacted at DEA as well as any guidance received.* ***The file also should indicate whether the order was shipped. DEA usually leaves the responsibility for determining whether to ship to the distributor***.[94] *(emphasis added)*

The metadata for this document indicates that it Is a 1997 manual. In any event, given the NWDA name on the front of the document, the document necessarily pre-dated the Association's name change to HDMA in 2000.

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[91] CAH_MDL2804_01465723, 01465734.

[92] HDA_MDL_000219360

[93] HDA_MDL_000219360, 000219435

[94] HDA_MDL_000219360, 000219437

This DEA direction to the National Wholesale Druggists' Association is consistent with the directives from Mr. Gitchel in 1984 from the earlier version of the Manual. It is also consistent with a Memorandum produced by the DEA dated December 8, 1993 that acknowledges the DEA's work with the NWDA on the specific issue of Suspicious Order Monitoring Systems.[95] Mr. Haislip, Director of the Office of Diversion Control within the DEA stated "The National Wholesale Druggist Association's (NWDA) Suspicious Order Monitoring System (SOM), which has been adopted by many distributors throughout the United States, can be an effective monitoring and reporting system, provided that the firms using it recognize their responsibility to actively monitor sales to detect suspicious orders,"[96] Mr. Haislip continued:

> What is of particular concern to me is the statement that appears on the reports submitted by the McKesson Corporation in Ft. Worth, Texas, i.e. "With the submission of this report, we are leaving to the DEA the final determination of whether they are suspicious or unusual." This position is unacceptable and clearly in contravention to the requirements of 21 CFR 1301.74(b). A registrant, whose own personnel are in the best position to determine what is excessive or unusual based on knowledge of their customers and usual purchasing practices, may not abrogate its responsibility to identify suspicious orders ***and to determine whether to ship or refuse to ship,*** the controlled substance order. The registrant must also report any suspicious orders as soon as possible to DEA. This has been conveyed to McKesson national management …[97](emphasis added)

2008 Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances.

In 2008 the HDMA posted on their website industry compliance guidelines that were titled, "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances." The introduction of the document contained this comment:

> At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support security of controlled substances they deliver to their customers. Due Diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.[98]

On October 17, 2008, DEA Chief Counsel Attorney Wendy H. Goggins sent a written statement to HDMA President and CEO John M. Gray commending the HDMA for their efforts

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[95] US-DEA-00026154

[96] US-DEA-00026154

[97] US-DEA-00026154, 00026155

[98] February 10, 2012 Declaration of Joseph Rannazzisi, CAH_MDL_PRIORPROD_DEA12_00014479, 00014512.

to assist their members in fulfilling the obligations regarding the Controlled Substance Act and corresponding regulations.[99]

The HDMA compliance guidelines document contains a general framework for a basic suspicious order monitoring system.[100] The document contains the following elements with accompanying suggested guidelines:

1. Know Your Customer Due Diligence
2. Monitoring for Suspicious Orders
3. Suspend/Stop an Order of Interest Shipment
4. Investigation of Orders of Interest
5. File Suspicious Order of Interest
6. Employees, Training and Standard Operating Procedures (SOPs)
7. Additional Recommendations
8. Glossary of Abbreviations

Although there are several areas or concerns which might render a suspicious order monitoring system less effective, the guidance provided by HDMA does contain several key elements that are consistent with compliance with 21 C.F.R. Section 1301.71(a) and 1301.74(b). Some of the keys areas of the guidance are the following:

1. Recommending distributors conduct thorough due diligence investigations that are documented and retained is essential in establishing a customer and providing a history for any further compliance actions or investigations.[101]

2. Providing guidance for a distributor to develop an electronic suspicious order system as detailed in a standard operation procedure, although not required by regulation, demonstrates HDMA recognizes the manual review of orders for deviations in size, frequency, or pattern would render it ineffective.[102]

3. Separating customers by business activity or class of trade is an essential system element. Further enhancement for monitoring and setting averages would be to form subgroups by the size of the customer.[103]

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[99] CAH_MDL_PRIORPROD_DEA12_00000825.

[100] CAH_MDL_PRIORPROD_DEA12_00000826.

[101] CAH_MDL_PRIORPROD_DEA12_00000826, 00000829-00000832.

[102] CAH_MDL_PRIORPROD_DEA12_00000826, 00000832.

[103] CAH_MDL_PRIORPROD_DEA12_00000826, 00000833.

4. Recommending of placing the controlled substances being monitored into groups or families provides a starting point for setting an average and monitoring. Only monitoring drug families and failing to evaluate the unusual order size, pattern, or frequency of any specific drug within a drug family has a much higher probability of failing to identify diversion of specific highly abused drugs.[104]

5. Thresholds may be set as averages shipped to a customer's facility that are consistent with that class of customer. Threshold are recommended to calculated for single orders and average monthly orders per family, per customer, and class of trade. Thresholds should utilize the information obtained in the due diligence investigation. A sales history of a minimum of six months and maximum of 24 months is recommended. Thresholds for new customer accounts should be established at the lowest level indicated by the due diligence investigation. An important component is the periodic review of cumulative orders for the customer to evaluate purchasing trends. [105] Note: The use of a six-month average does not provide a sufficient purchase history for establishing accurate thresholds.

6. A distributor should consider allowing use of alternative criteria, outside of the suspicious order system, to be utilized to identify a suspicious order.[106]

7. On page 9, Section III in the section titled, SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT, there is clear guidance from HDMA of what action should be taken by a distributor when an order exceeds a threshold which is contained in the following statement, "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[107]

8. Recommending that if an order meets or exceeds a threshold the distributor examine the order further. The examination aids the distributor in deciding to either fill the order and ship or to continue to hold the order. This section also states, "Further examination will also aid in determining whether the and when to report the order to DEA under 21 C.F.R. Section 1301.74(b)."[108]

9. The following statement is made in regard to an order of interest, "The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest."[109]

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[104] *Id.*

[105] *Id.*

[106] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000834.

[107] *Id.*

[108] *Id.*

[109] *Id.*

10. A customer interview should be conducted in regards to order. Any information provided by the customer should be verified and documented.[110]

11. All investigation conducted by the distributor should be "fully documented," and all records retained in an appropriate section. A critical element of guidance states the following, "The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." The statement should be signed and dated by the reviewer."[111]

12. An order determined to be "suspicious" should be reported immediately upon being so determined.[112]

13. The following guidance was provided for the content of the standard operating policy:

a. Describe how an initial review and investigation will be conducted;

b. Reflect the distributor's and its customers' business conditions;

c. Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;

d. Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";

e. Define a process for reporting to DEA under 21 C.F.R. Section 1301.74(b); and

f. Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.[113]

14. If a distributor concludes an order is suspicious after conducting an investigation it is recommended the distributor make a determination whether it will subject future orders from the same customer for the same drug product to more rigorous scrutiny and/or consider whether to cease filling all future orders of that drug product or all controlled substances.[114]

L. DEA CHEMICAL HANDLERS MANUAL

Cardinal Health (and others) have responded to discovery referencing the DEA's Chemical Handlers Manual and/or the 1998 Reno Report as "guidance" provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including

[110] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000835.

[111] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000836.

[112] *Id*.

[113] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000837.

[114] *Id*.

prescription opiates.[115] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[116]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

M. MAINTENANCE OF EFFECTIVE CONTROLS AGAINST DIVERSION OF CONTROLLED SUBSTANCES

Registrants engaged in actively distributing controlled substances must implement measures to comply with the legal and regulatory requirements. These measures should be documented as a standard operating policy for the company and be distributed to all relevant employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical first step to ensures a potential customer has a business plan consistent with compliance with the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:
        - Past history of DEA registration to determine compliance history
        - Check of state and local licensure compliance.
        - Compliance history with state medical/pharmacy board
        - Review the business plan to determine legitimacy of the customer

[115] *See*, *e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[116] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

- Identify any affiliation with pain management doctors
- Review percentage of controlled substance business
- Identify any other distributors providing controlled substances
- Review the percentage of cash payments and insurance payments
- Review of pharmacy utilization reports
- On-site inspection of customer
- Internet search to determine any negative information

- 21 C.F.R. §1301.74(b) requires all manufacturers and distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances. This regulation states that suspicious orders include orders of an unusual size, orders deviating substantially for a normal pattern, and orders or an unusual frequency. The regulation further states that a registrant shall inform the local DEA Division Office of suspicious orders when discovered by the registrant. The regulation indicates it is the responsibility of the registrant to **design** and **operate** a suspicious order monitoring system. The design of a suspicious order system must clearly identify when a suspicious order is identified by the system. A system that establishes thresholds that are legitimate needs of a customer identified through a comprehensive "know your customer" should consider any orders exceeding that threshold as a suspicious order. The identified order should not be shipped and should be reported to the DEA. The subsequent shipping of that order would be after a due diligence investigation has determined the order is being shipped for legitimate use. An effective suspicious order system contains many components which should include, but not be limited to, the following:
  - Customer Types – Customers should be placed into customer types based on the business activity identified through the due diligence documentation.
  - Scope of Practice – The system should monitor and/or restrict customers to only allow the ordering of controlled substances by schedule and type which have been identified as required for the legitimate medical needs of the practice.
  - Customer Tiers/Groups – Customers who have been placed into customer types should be segregated by size into a minimum of three groups, based on the volume of their ordering history as identified through the due diligence documentation.
  - Drug Types – To be effective, a suspicious order monitoring system should design drug types with more specificity that by drug group or drug code. Monitoring controlled substances only by the drug code or drug family is too broad and reduces the effectiveness of the system. Thresholds should also be designed for those controlled substances identified with a higher probability of being targeted for diversion.
  - Thresholds – A distributor must identify the amount of controlled substances required by a customer for the legitimate operation of their business based on the registrant's knowledge of the customers business model, due diligence investigation, and comparison of purchase amounts by other similar customers. Thresholds should be calculated based on the history of usage of customer for a period of at least 12 months.

- Population – The geographic distribution of controlled substances should be analyzed with relevant population information of available end users. The cumulative amount of controlled substances being distributed by a registrant to a geographic area or region should be monitored to ensure it is consistent with legitimate population consumption. Customers who identify activity of filling prescriptions from patients traveling from outside the area require a thorough due diligence type investigation including the review of dispensing records (without patient information) to confirm the legitimacy of the activity.
- Pattern of Orders – Reviewing orders to determine if there are patterns of ordering of controlled and non-controlled drugs with a comparison with relevant industry information on the most frequently prescribed drugs. If the review reveals an ordering pattern that deviates from established levels or from what would be normal for another similarly situated customer this could indicate potential diversion.
- Pattern of Orders – Reviewing orders to determine if the controlled substances are ordered in combinations of frequently abused drugs. As an example, purchasing the combination of oxycodone or hydrocodone products with Soma, Valium, and/or Xanax. The pattern of ordering of known highly abused controlled substances in comparison of other drugs can indicate diversion.
- Frequency of Orders – Reviewing order to determine if the frequency of orders for controlled substances is increasing disproportionately for specific controlled substances that have been identified as being highly diverted.
- Geographic Distribution – The density of like businesses in geographic areas should be reviewed. Further, there should be a comparison of like customers in similarly situated geographic areas for deviation of volume and/or pattern of controlled substance orders. The system should identify large volume of controlled substances consistently being received from a customer(s) in a state, county and city/township that does not have the appropriate customer base density.

- A robust and well-documented due diligence program is key for every compliance system to identify suspicious orders of controlled substances. When orders of controlled substances are identified due to factors such as size, pattern, or frequency, those orders may only be shipped if any suspicion is dispelled after adequate due diligence is conducted and it is determined that such orders are not likely to be diverted for illicit purposes. The elements and procedures involved in a due diligence compliance program for suspicious orders should be contained in a standard operation policy and should be readily available to all employees whose responsibilities touch on suspicious order monitoring. Characteristics of a robust due diligence program should include the following:

  - An established procedure and criteria for setting threshold quantities.
  - The person or department who is responsible for approving threshold quantities is specifically identified.
  - A procedure for adjusting threshold quantities that requires thorough review and documentation.

- Justification for the increase or decrease of thresholds documented by the registrant, and made after a review of factors such as the following:
  - Analysis of historical orders from the customer as well as any previous adjustments in thresholds and the justification previously provided;
  - Analysis of the patient population serviced by the customer;
  - Analysis of the physician population serviced by the customer;
  - Analysis of the results of an adequate on-site customer review program; and
  - Analysis of other factors that could indicate to the registrant whether or not controlled substances are likely to be diverted for illicit purposes.
- Compliance review programs that have independent authority from other corporate entities/divisions to review thresholds as well as to approve or disapprove customers or threshold adjustments.
- Sales role (if any) in the compliance review program must be appropriately managed.
- On-site review includes the acquisition and review of utilization report.
- Request for threshold changes necessitates an on-site review.
- The person(s) is specifically identified who is responsible for reporting suspicious orders to the DEA.
- Orders reported as suspicious that are subsequently shipped by the registrant have sufficient due diligence review being conducted and documented prior to distribution.
- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.
- Acquisition and review of prescriber reports to determine any unusual prescribing patterns or practices, to be analyzed for the following information:
  - A disproportionate ratio of controlled to non-controlled substances prescriptions relative to the prescriber's field of practice or local population.
  - A prescriber issuing prescriptions for high volumes of controlled substances or disproportionately large volumes of controlled substances relative to the prescriber's field of practice.
  - Large variances or sharp increases in controlled substances prescribing.
  - A high ratio of high dose or highly abused controlled substances prescriptions issued by a prescriber when compared to other strengths of the same drug type.

- Whether a practitioner or small number of practitioners are responsible for issuing a large amount of controlled substances prescriptions that are dispensed by the pharmacy.
- Prescriber who issues similar prescriptions of the same type, strength, and quantity with the same directions for a large number of patients.
- Prescriptions issued by a prescriber whose practice is an unusual distance from the pharmacy.
- Prescriptions issued for an unusual volume or pattern of antianxiety/antidepressants along with opioids.
- A high percentage of controlled substances paid for with cash/credit cards.
- Practitioners who issue prescriptions for a "cocktail" of controlled substances which are known in the medical and pharmacy professions as being favored by drug-seeking individuals.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions and information of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to make informed decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all. [117]

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships the order anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. Additionally, chain pharmacy

[117] Thomas Prevoznik testified on behalf of the DEA that it would be "very hard to maintain effective controls" without maintaining and retaining due diligence files. *See* Depo. of Prevoznik (Vol III; May 17, 2019), pp. 994-996.

distibutors, such as those considered in this report, have total visibility of all orders placed by their affiliated pharmacies to any distributor. Therefore chain pharmacy distributors must consider and take into account orders placed to third-party distributors when determining whether orders from affiliated pharmacies are suspicious. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

IV. Identifying Suspicious Orders Distributed in Lake and Trumbull Counties, Ohio

I have described in this report the ways in which the defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed seven suspicious order methodologies, some of which were utilized by one or more of the defendants. These methodologies are identified in the April 16, 2021 report of Craig J. McCann, Ph.D., CFA as "Maximum Monthly, Trailing Six-Month Pharmacy Specific Threshold," "Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold," "Twice Trailing Twelve-month Average," "Three Times Trailing Twelve-month Average," "Maximum 8,000 Dosage Units Monthly," "Maximum Daily Dosage Units," and "Maximum Monthly Trailing Six Month Specific Threshold on Rolling 30 Days." Dr. McCann applied these methodologies to each defendant's dsitributions of opioids into Lake and Trumbull County as well as, separately, to opioid orders from all distributors to each defendant's affiliated chain pharmacies. The purpose of each system was to identify suspicious orders that should not have been shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.[118]

With the exception of the methodology titled Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold,[119] under each of these methodologies, once an order by a pharmacy is flagged and the distributor does not conduct sufficient due diligence to dispel the suspicion of diversion, each subsequent order by that pharmacy is also flagged. The failure to conduct adequate due diligence on the initial triggering order, means that all subsequent orders by that pharmacy are likewise suspicious. This is consistent with the testimony of Thomas Prevoznik

[118] I utilized these Defendants - CVS, Walgreens, Walmart, HBC/Giant Eagle, and Rite Aid - as they constitute a significant majority of the opioid pills delivered into CT3 according to the data described in the Expert Report of Craig J. McCann.

[119] Under the Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold, when a transaction causes the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to the pharmacy in any one of the six preceding months, the dosage units of highest month in the preceding six months becomes threshold which is then applied in all subsequent months.

who testified on behalf of the DEA that distributors should not ship a suspicious order and should terminate all future sales to that same customer until they can rule out that diversion is occurring.[120]

The following charts provide the results of each methodology applied to orders placed by pharmacies in Lake and Trumbull Counties to each distributor.[121]

A. Methodology: Maximum Monthly, Trailing 6 Month Pharmacy Specific Threshold

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	6,632,500(91.8% of total dosage units)
Walgreens	6,684,800 (93.6% of total dosage units)	5,612,670 (91.1% of total dosage units)
Rite Aid	n/a	2,873,820 (90.3% of total dosage units)
Walmart	5,122,300 (97.0% of total dosage units)	3,787,700 (96.6% of total dosage units)
HBC/Giant Eagle	n/a	3,064,800 (86.5% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	6,715,300 (90.6% of total dosage units)
Walgreens	3,816,600 (94.9% of total dosage units)	7,959,130 (94.1% of total dosage units)
Rite Aid	n/a	13,048,040 (92.4% of total dosage units)
Walmart	1,720,800 (93.4% of total dosage units)	3,332,400 (89.1% of total dosage units)
HBC/Giant Eagle	n/a	6,444,200 (86.6% of total dosage units)

[120] Depo. of Thomas Prevoznik (Vol. II), 627:7-629:15.

[121] McCann Report, Appendix 8.

B. Methodology Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	2,216,600 (30.7% of total dosage units)
Walgreens	2,934,600 (41.1% of total dosage units)	1,483,730 (24.1% of total dosage units)
Rite Aid	n/a	307,060 (9.6% of total dosage units)
Walmart	3,054,600 (57.8% of total dosage units)	1,553,400 (39.3% of total dosage units)
HBC/Giant Eagle	n/a	454,800 (12.8% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	795,700 (10.7% of total dosage units)
Walgreens	2,389,100 (59.4% of total dosage units)	3,170,720 (37.5% of total dosage units)
Rite Aid	n/a	3,757,200 (26.6% of total dosage units)
Walmart	857,800 (46.6% of total dosage units)	383,600 (10.3% of total dosage units)
HBC/Giant Eagle	n/a	532,000 (7.1% of total dosage units)

C. Methodology: Twice Trailing Twelve-Month Average

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	0
Walgreens	5,256,900 (73.6% of total dosage units)	0
Rite Aid	n/a	971,260 (30.5% of total dosage units)

Walmart	2,996,900 (83.3% of total dosage units)	0
HBC/Giant Eagle	n/a	0

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	0	3,532,600 (47.7% of total dosage units)
Walgreens	1,489,500 (37.0% of total dosage units)	2,202,520 (26.0% of total dosage units)
Rite Aid	0	11,710,440 (82.9% of total dosage units)
Walmart	225,100 (19.8% of total dosage units)	1,224,000 (41.1% of total dosage units)
HBC/Giant Eagle	0	4,233,400 (56.9% of total dosage units)

D. Methodology: Three Times Trailing Twelve-Month Average

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	0
Walgreens	3,612,100 (50.6% of total dosage units)	0
Rite Aid	n/a	0
Walmart	2,263,100 (62.9% of total dosage units)	0
HBC/Giant Eagle	n/a	0

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	1,313,900 (17.7% of total dosage units)
Walgreens	0	0
Rite Aid	n/a	7,035,480 (49.8% of total dosage units)
Walmart	0	0

HBC/Giant Eagle	n/a	0

E. Methodology: Maximum 8,000 Dosage Units Monthly

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	6,612,100 (91.5% of total dosage units)
Walgreens	6,827,400 (95.6% of total dosage units)	5,854,690 (95.0% of total dosage units)
Rite Aid	n/a	1,899,220 (59.7% of total dosage units)
Walmart	4,722,200 (89.4% of total dosage units)	3,317,000 (84.6% of total dosage units)
HBC/Giant Eagle	n/a	3,070,700 (86.6% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	7,363,500 (99.4% of total dosage units)
Walgreens	3,550,000 (88.3% of total dosage units)	8,348,630 (98.7% of total dosage units)
Rite Aid	n/a	13,991,640 (99.1% of total dosage units)
Walmart	887,200 (48.2% of total dosage units)	3,388,300 (90.6% of total dosage units)
HBC/Giant Eagle	n/a	7,399,500 (99.4% of total dosage units)

F. Methodology: Maximum Daily Dosage Units

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	7,227,000 (100.0% of total dosage units)
Walgreens	7,089,900 (99.3% of total dosage units)	6,161,370 (100.0% of total dosage units)

Rite Aid	n/a	3,182,020 (100.0% of total dosage units)
Walmart	5,187,800 (98.2% of total dosage units)	3,778,200 (97.6% of total dosage units)
HBC/Giant Eagle	n/a	3,544,400 (100.0% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	7,410,200 (100.0% of total dosage units)
Walgreens	3,977,700 (98.9% of total dosage units)	8,455,230 (100.0% of total dosage units)
Rite Aid	n/a	14,118,240 (100.0% of total dosage units)
Walmart	1,754,700 (95.2% of total dosage units)	3,547,000 (99.4% of total dosage units)
HBC/Giant Eagle	n/a	7,443,400 (100.0% of total dosage units)

G. Methodology: Maximum Monthly Trailing Six Month Specific Threshold on Rolling 30 Days

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	6,863,100 (95.0% of total dosage units)
Walgreens	6,805,800 (95.3% of total dosage units)	5,820,770 (94.5% of total dosage units)
Rite Aid	n/a	3,008,220 (94.5% of total dosage units)
Walmart	5,167,200 (97.8% of total dosage units)	3,800,000 (97.0% of total dosage units)
HBC/Giant Eagle	n/a	3,203,300 (90.4% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	n/a	6,909,400 (93.2% of total dosage units)
Walgreens	3,846,900 (95.6% of total dosage units)	8,065,530 (95.4% of total dosage units)
Rite Aid	n/a	13,464,940 (95.4% of total dosage units)
Walmart	1,766,600 (95.92% of total dosage units)	3,479,000 (93.0% of total dosage units)
HBC/Giant Eagle	n/a	6,713,300 (90.2% of total dosage units)

The following charts provide the results of each methodology applied to orders placed by each distributor's pharmacies to all distributors.[122]

H. Methodology: Maximum Monthly, Trailing 6 Month Pharmacy Specific Threshold

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	8,946,500 (96.3% of total dosage units)	7,275,720 (93.4% of total dosage units)
Walgreens	8,404,200 (94.1% of total dosage units)	6,342,950 (92.6% of total dosage units)
Rite Aid	5,664,100 (94.7% of total dosage units)	3,399,950 (91.5% of total dosage units)
Walmart	3,623,600 (95.7% of total dosage units)	3,126,100 (95.9% of total dosage units)
HBC/Giant Eagle	4,479,800 (94.6% of total dosage units)	5,780,820 (95.6% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	2,744,300 (89.4% of total dosage units)	7,140,230 (89.0% of total dosage units)

[122] McCann Report, Appendix 8.

Walgreens	5,595,400 (95.6% of total dosage units)	9,246,860 (94.7% of total dosage units)
Rite Aid	8,625,090 (94.2% of total dosage units)	15,071,670 (92.9% of total dosage units)
Walmart	1,047,600 (89.2% of total dosage units)	2,737,530 (87.3% of total dosage units)
HBC/Giant Eagle	4,480,380 (89.1% of total dosage units)	13,524,310 (94.3% of total dosage units)

I. Methodology Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	5,814,900 (62.6% of total dosage units)	2,696,140 (34.6% of total dosage units)
Walgreens	3,321,300 (37.2% of total dosage units)	1,574,900 (23.0% of total dosage units)
Rite Aid	2,272,600 (38.0% of total dosage units)	493,720 (13.3% of total dosage units)
Walmart	2,214,400 (58.5% of total dosage units)	1,403,090 (43.0% of total dosage units)
HBC/Giant Eagle	2,784,600 (58.8% of total dosage units)	2,765,530 (45.7% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	640,500 (20.9% of total dosage units)	1,196,120 (14.9% of total dosage units)
Walgreens	3,628,600 (62.0% of total dosage units)	3,887,220 (39.8% of total dosage units)
Rite Aid	3,471,170 (37.9% of total dosage units)	4,607,550 (28.4% of total dosage units)
Walmart	360,100 (30.7% of total dosage units)	360,430 (11.5% of total dosage units)
HBC/Giant Eagle	894,700 (17.8% of total dosage units)	4,131,580 (28.8% of total dosage units)

J. Methodology: Twice Trailing Twelve-Month Average

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	6,764,300 (72.8% of total dosage units)	994,330 (12.8% of total dosage units)
Walgreens	6,645,200 (74.4% of total dosage units)	0
Rite Aid	4,419,100 (73.9% of total dosage units)	1,146,940 (30.9% of total dosage units)
Walmart	3,156,900 (83.4% of total dosage units)	0
HBC/Giant Eagle	1,023,000 (21.6% of total dosage units)	0

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	0	4,968,330 (61.9% of total dosage units)
Walgreens	2,675,100 (45.7% of total dosage units)	2,624,510 (26.9% of total dosage units)
Rite Aid	6,346,530 (69.3% of total dosage units)	12,052,750 (74.3% of total dosage units)
Walmart	284,900 (24.3% of total dosage units)	1,282,300 (40.9% of total dosage units)
HBC/Giant Eagle	2,844,080 (56.6% of total dosage units)	7,960,310 (55.5% of total dosage units)

K. Methodology: Three Times Trailing Twelve-Month Average

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	2,944,500 (31.7% of total dosage units)	0
Walgreens	3,539,000 (39.6% of total dosage units)	0

Rite Aid	3,888,300 (65.0% of total dosage units)	0
Walmart	2,924,200 (77.2% of total dosage units)	0
HBC/Giant Eagle	610,600 (12.9% of total dosage units)	0

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	0	1,420,600 (17.7% of total dosage units)
Walgreens	312,000 (5.3% of total dosage units)	0
Rite Aid	2,590,130 (28.3% of total dosage units)	6,547,290 (40.4% of total dosage units)
Walmart	119,700 (10.2% of total dosage units)	0
HBC/Giant Eagle	0	3,206,350 (22.4% of total dosage units)

L. Methodology: Maximum 8,000 Dosage Units Monthly

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	8,288,000 (89.2% of total dosage units)	7,248,120 (93.0% of total dosage units)
Walgreens	8,632,200 (96.7% of total dosage units)	6,539,030 (95.4% of total dosage units)
Rite Aid	4,878,000 (81.6% of total dosage units)	2,903,290 (78.1% of total dosage units)
Walmart	3,217,500 (85.0% of total dosage units)	2,672,200 (81.9% of total dosage units)
HBC/Giant Eagle	3,403,600 (71.9% of total dosage units)	4,953,700 (81.9% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)

CVS	2,655,100 (86.5% of total dosage units)	7,975,890 (99.4% of total dosage units)
Walgreens	5,350,300 (91.4% of total dosage units)	9,723,860 (99.5% of total dosage units)
Rite Aid	7,710,490 (84.2% of total dosage units)	16,112,570 (99.3% of total dosage units)
Walmart	261,600 (22.3% of total dosage units)	2,901,530 (92.5% of total dosage units)
HBC/Giant Eagle	3,880,180 (77.2% of total dosage units)	14,237,110 (99.3% of total dosage units)

M. Methodology: Maximum Daily Dosage Units

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	9,202,100 (99.1% of total dosage units)	7,787,920 (100.0% of total dosage units)
Walgreens	8,876,500 (99.4% of total dosage units)	6,852,650 (100.0% of total dosage units)
Rite Aid	5,870,000 (98.1% of total dosage units)	3,715,650 (100.0% of total dosage units)
Walmart	3,679,800 (97.2% of total dosage units)	3,168,900 (97.2% of total dosage units)
HBC/Giant Eagle	4,580,600 (96.7% of total dosage units)	5,884,320 (97.3% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	3,044,300 (99.2% of total dosage units)	8,024,690 (100.0% of total dosage units)
Walgreens	5,807,000 (99.2% of total dosage units)	9,766,260 (100.0% of total dosage units)
Rite Aid	9,103,390 (99.4% of total dosage units)	16,219,170 (100.0% of total dosage units)
Walmart	1,085,100 (92.4% of total dosage units)	3,120,630 (99.5% of total dosage units)
HBC/Giant Eagle	4,920,380 (97.9% of total dosage units)	14,340,510 (100.0% of total dosage units)

N. Methodology: Maximum Monthly Trailing Six Month Specific Threshold on Rolling 30 Days

Lake County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	9,050,500 (97.4% of total dosage units)	7,455,120 (95.7% of total dosage units)
Walgreens	8,541,700 (95.6% of total dosage units)	6,504,150 (94.9% of total dosage units)
Rite Aid	5,747,300 (96.1% of total dosage units)	3,539,750 (95.2% of total dosage units)
Walmart	3,655,700 (96.5% of total dosage units)	3,137,100 (96.2% of total dosage units)
HBC/Giant Eagle	4,560,100 (96.3% of total dosage units)	5,832,420 (96.4% of total dosage units)

Trumbull County: 2006-2014

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
CVS	2,813,600 (91.6% of total dosage units)	7,586,250 (94.5% of total dosage units)
Walgreens	5,666,100 (96.8% of total dosage units)	9,371,260 (95.9% of total dosage units)
Rite Aid	8,778,690 (95.9% of total dosage units)	15,498,270 (95.6% of total dosage units)
Walmart	1,096,300 (93.4% of total dosage units)	2,868,230 (91.5% of total dosage units)
HBC/Giant Eagle	4,744,280 (94.4% of total dosage units)	13,689,510 (95.4% of total dosage units)

I have been asked to identify the number of opioid pills that entered Lake and Trumbull Counties unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.[123] However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug*

[123] This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the distributor and manufacturer specific sections of this report.

Enforcement Administration, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[124] *See* Methodology A above. Pursuant to *Masters,* "as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence" *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT3 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions.

V. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

A. CVS Health

Distribution Center	DEA Registrant Number
CVS Indiana, L.L.C. 7590 Empire Drive, Doors 116-123 Indianapolis, Indiana 6219	RH0197170
CVS Rx Services, Inc. 150 White Wagon Road Chemung, New York 14825	RC0415871
CVS TN Distribution, L.L.C. 10017 Kingston Pike Knoxville, Tennessee 37922	PR0205559

Transactional Data:

Date range: 2006-2014 (ARCOS)

Volume:

[124] This approach does not take into consideration unusual pattern or frequency.

Trumbull[125]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	0	0	0
Hydrocodone	7,410,200	33,965,666	33,966

Lake[126]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	0	0	0
Hydrocodone	7,227,700	29,480,065	29,480

1. Court ordered SOMS Discovery Disclosure:

- *CVS HEALTH CORPORATION'S OBJECTIONS AND RESPONSES TO PLANTIFFS' FIRST SET OF INTERROGATORIES (6/18/18)*
- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERRROGATORIES NO. 1-6, 8-10, 13, 15-18, 20-21 AND 30 OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (9/10/18)*
- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORIES NO. 11, 13 AND 30 OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (11/30/18)*
- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORIES NO. 7, 12, 14, 15, 17, 19, AND 22-29 OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (1/25/19)*
- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORY NO. 15. OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (3/4/19)*
- *CVS HEALTH CORPORATION'S OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS (6/18/18)*
- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO REQUESTS NO. 1-6 AND 9 –33 OF PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS (9/27/18)*
- *CVS RX SERVICES, INC.'S AND CVS INDIANA, L.L.C.'S OBJECTIONS AND RESPONSES TO PLAINTIFFS' (FIRST) COMBINED DISCOVERY REQUESTS TO NATIONAL RETAIL PHARMACY DEFENDANTS (11/30/18).*

[125] *See* Expert Report of Craig J. McCann, Ph.D, CFA, Appendix 8.

[126] *Id.*

- *CVS INDIANA L.L.C. AND CVS RX SERVICES, INC. DISCOVERY RULING NO. 15 SUPPLEMENT (2/22/19)*

- *CVS INDIANA L.L.C.'S AND CVS RX SERVICES, INC.'S WRITTEN RESPONSE TO TOPIC 1 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (11/8/18)*

- *CVS'S WRITTEN RESPONSES TO TOPICS 8, 9, 12, 13 AND 14 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (11/15/18)*

- *CVS INDIANA L.L.C.'S AND CVS RX SERVICES, INC.'S PARTIAL WRITTEN RESPONSE TO TOPIC 2 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (11/19/18)*

- *CVS'S WRITTEN RESPONSES TO TOPICS 2, 4, 10, 16 AND 17 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (1/14/19)*

- *OBJECTIONS AND RESPONSES BY DEFENDANTS CVS INDIANA L.L.C., CVS ROX SERVICES, INC., CVS TN DISTRIBUTION, L.L.C., CVS PHARMACY, INC., AND OHIO CVS STORES, L.L.C. TO INTERROGATORIES NOS. 1, 2, 3, 6, AND 8 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS (7/13/2020)*

- *OBJECTIONS AND RESPONSES BY DEFENDANTS CVS INDIANA L.L.C., CVS RX SERVICES, INC., CVS TN DISTRIBUTION, L.L.C., CVS PHARMACY, INC., AND OHIO CVS STORES, L.L.C., TO REQUESTS NOS. 4, 6, 7, 8, 10, 19, 24, 26, AND 30 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE REQUESTS FOR PRODUCTION TO CHIAN PHARMACY DEFENDANTS (7/13/2020)*

- *OBJECTIONS AND RESPONSES BY DEFENDANTS CVS INDIANA L.L.C., CVS RX SERVICES, INC., CVS TN DISTRIBUTION, L.L.C., CVS PHARMACY, INC., AND OHIO CVS STORES, L.L.C., TO INTERROGATORIES NOS. 4, 5, 7, AND 9-13 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS (7/27/2020)_*

- *OBJECTIONS AND RESPONSES BY DEFENDANTS CVS INDIANA L.L.C., CVS RX SERVICES, INC., CVS TN DISTRIBUTION, L.L.C., CVS PHARMACY, INC., AND OHIO CVS STORES, L.L.C. TO REQEUSTS NOS. 1-3, 5, 9, 11-18, 20-23, 25, 27-29, AND 31-33 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE REQUESTS FOR PRODUCTION TO CHAIN PHARMACY DEFENDANTS (7/27/2020)*

- *CVS'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORIES NOS. 1, 2, 3, 8, 10, AND 11 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS (10/16/2020)*

- *CVS'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORIES NOS. 10 AND 11 OF PLAINTIFFS' (FIRST) COMBINED TRACE THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS (10/30/2020)*

- *CVS'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORIES NOS. 3, 4, 8, 9,10, AND 11 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS (1/29/2021)*

- *CVS'S AMENDED OBJECTIONS AND RESPONSES TO REQUESTS NO. 1, 14, 19,24, 27, 28, 31, 32, AND 33 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE REQUESTS FOR PRODUCTION TO CHAIN PHARMACY DEFENDANTS (1/29/2021)*

- *CVS'S OBJECTIONS AND RESPONSES TO PLAINTIFFS' SECOND COMBINED TRACK THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS (1/29/2021)*

2. SOMS Corporate Policy Disclosed:

It is my understanding that in response to the Combined Discovery Request No. 2, CVS listed Bates stamp ranges of documents but failed to identify with specificity the SOM policy and/or procedure and/or the date the policy and/or procedure was in effect. Additionally, I understand that portions of the SOMS Corporate Policy were disclosed in the written responses to other discovery, the Rule30(b)(6) testimony offered by Mark Vernazza and the testimony of other deponents.

CVS's first written controlled drug operating procedures were circulated on December 1, 2007. The 2007 document was titled "CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manual."[127] The "standard operating procedures were prepared in response to a need for a single source of current information for CVS regarding DEA policies and requirements of the Comprehensive Drug Abuse Prevention Act."[128] Although the "Suspicious Order Monitoring (SOM)" section of the standard operating procedures contained some language, albeit admittedly incomplete as outlined in the document, Mark Vernazza, the CVS 30(b)(6) witness and CVS in-house attorney, testified that the suspicious order monitoring section of the

[127] CVS-MDLT1-000025206-000025259.

[128] CVS-MDLT1-000025207.

standard operating procedures was essentially a draft or placeholder and was not the policy that was necessarily in place at the time.[129]

Despite admitting in 2007 a need existed for a "single source of current information for CVS regarding DEA policies," CVS did not insert a written SOM policy into the standard operating procedures until August 25, 2010.[130] In other words, CVS had no written SOM policies until August 25, 2010.

The August 25, 2010 SOM section of the Standard Operating Procedures is disjointed and includes many inconsistencies.[131] For example, the title headings found within the Table of Contents for the SOM section do not actually match the title headings used in the document.[132] The page numbers in the Table of Contents for the SOM section are incorrect. The wording of the SOM section itself is inaccurate, for example, indicating that within the next month the critical Item Review Report ("IRR") examination process would be transitioned to each pharmacy DC and outlining procedures to be followed once that happens.[133] Yet the IRR review process was never transitioned to each individual DC.

The Controlled Drug – DEA Standard Operating Procedures Manual for the pre-2014 SOM system was amended multiple times between 2010 and 2013, with the last revision dated April 18, 2013.[134] None of these amendments made significant changes to the SOM section, other than the March, 11, 2011 revision stating the IRR review was centralized in Knoxville, TN,[135] and later revisions identified individuals who were supposed to fulfill certain DEA obligations within CVS but who were not.[136] An example of this is the testimony of Amy Propatier who admitted that she was listed as the CVS DEA Compliance Coordinator in the Controlled Drug – DEA Standard Operating Procedures Manuals but that title was only for reference in the Standard Operating procedures and was not her real job position. She also testified that as the CVS DEA Compliance Coordinator the only thing she did related to suspicious order monitoring was updating the standard operating procedures manual.[137]

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[129] Vernazza Depo., 214:11–215:10; 219:4–221:13; 305:16–306:5; CVS-MDLT1-000025206–000025259.

[130] Vernazza Depo., 305:16–306:5; CVS-MDLT1-000008964–9032.

[131] Vernazza Depo., 300:6- 312:20 (Mark Vernazza denies that this is the case.); CVS-MDLT1-000089188; CVS-MDLT1-000057751.

[132] *See* titles found on CVS-MDLT1–00008966 compared with titles used at CVS-MDLT1-00009003.

[133] *See* CVS-MDLT1-00009004: "During the month of September, 2010, the report will be transitioned to each pharmacy DC and the following procedures will occur."

[134] CVS-MDLT1-00008572-000008635.

[135] CVS-MDLT1-00008413-00008482.

[136] See for example names inserted into the 5/6/11 Controlled Drug – DEA Standard Operating Procedures Manual found at CVS-MDLT1-00003177-3242.

[137] Propatier Depo., 79:15 – 81:2.

The Controlled Drug – DEA Standard Operating Procedures Manual purported to be the "single source of current information for CVS regarding DEA policies,"[138] however, CVS did author other shorter policies that appear not to have been implemented or, at least, not consolidated with the "single source" SOP. Many of these shorter policies appear to be the same or very similar to the information contained within the CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manuals.[139]

On February 29, 2012, the first Work Instructions for Loss Prevention Analyst, outlining how to perform IRR/SOM analysis was instituted.[140] This appears to be the first written instructions informing analysts how to perform an IRR review. The IRR is the primary SOM process, and yet CVS neglected to provide written instructions outlining how to perform that critical review from its initial use in mid-2009 until February 29, 2012.

The DEA was on-site at CVS in August, 2013 conducting an investigation.[141] The content of the CVS letter to Mr. Gillen, who was the Diversion Group Supervisor for that DEA office, indicates the purpose was a regulatory investigation. This is an investigation of compliance with DEA security and record-keeping regulations and an accountability audit of selected controlled substances. Normally the DEA conducts a "closing" upon completing the investigation, but according to the CVS letter, it still had not occurred as of November 21, 2013.

The CVS letter indicates that CVS and Mr. Gillen had a discussion on November 14, 2013 and Gillen had some concerns about the SOM process. According to the CVS letter, Gillen was going to report to his Program Manager in Chicago that CVS had no reporting structure in place.[142] In response to Gillen's inquiries, Mark Nicastro sent a packet of information to the DEA. [143] [144] As part of the packet, CVS provided the DEA with what it claimed was its Standard Operating Procedure for Suspicious Order Monitoring but it provided an outdated version of the policy when a more recent edition was available. Specifically, on January 7, 2013 the "SOM Process—Stop Order/Order Resumption SOP" was drafted.[145] Revision number three of this document was dated

[138] CVS-MDLT1-000025206-000025259, 000025207.

[139] See PSE and Control Drug Policy & Procedures Template Logistics IRR Analyst – Suspicious Transactions (21 USC 830(b)(1) Effective Date: June 28, 2011. CVS-MDLT1-000083552-83556.

[140] CVS-MDLT1-0000020426–20428.

[141]CVS-MDLT1-000010202.

[142] CVS-MDLT1-000010202.

[143] CVS-MDLT1-000010201 – 10212.

[144] The document as provided to Mr. Gillen representing suspicious orders reported by CVS to the DEA has insufficient information that renders it useless. The database does not identify the date of order, DEA registration #, type and strength of drug and/or NDC #.(CVS-MDLT1-000010209).

[145] CVS MDLT1-000028391-000028393. This document was a rough draft. See CVSMDLT1-000028390.

three days later on January 10, 2013.[146] Evidence suggests that this was also a draft,[147] but CVS sent this document to the DEA on November 21, 2013 representing it as the Standard Operating Procedure for Suspicious Order Monitoring.[148] A final revision of the Stop Order/Order Resumption SOP was created on March 28, 2013.[149] In other words, CVS represented to the DEA that the January 10th version was the standard operating procedures for suspicious order monitoring, even though it had already been revised and replaced. Moreover, each version of the "CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manuals" indicate that they are the "single source" for DEA policies, and they differ from the stand alone Standard Operating Procedure for Suspicoius Order Monitoring document provided to the DEA.

Significant differences exist between the January 10th version provided to the DEA on November 21, 2013 and the March 28, 2013 version that according to the documents was actually the version in place as of November 21, 2013. The January 10, 2013 CVS document (hereinafter referred to as Document A) provided to the DEA on November 21, 2013, was titled, "CVS / Corporate Logistics, External Documents, SOM Process – Stop Orders / Order Resumption SOP" with a Current Revision Date of 01/10/2013 and assigned Revision Number 03.[150] The more recent CVS policy that, according to the documents was in place on November 21, 2013 and should have been sent to the DEA (hereinafter referred to as Document B) was titled, "CVS / Corporate Logistics, External Documents, SOM Process – Stop Orders / Order Resumption SOP" with a Current Revision Date of 03/28/2013 and assigned Revision Number 04.[151] It should be noted both policies contain the following statement underlined in bold font, "**THIS IS A CONTROLLED DOCUMENT – USE LATEST REVISION**."

The most significant difference was with regard to the due diligence process. In Document A in the "Identify and Hold" Section of the policy the second paragraph contains the following language:

> *Once an order of interest is identified, the SOM Analyst will complete all necessary due diligence and the SOM Manager will be notified to review the order. Due diligence will include, but is not limited to: contacting the Pharmacist, reviewing dispensing data, reviewing prior ordering data, comparing the quantity of controlled substances to non-controlled substances, determining if prescriptions for cocktails are being presented to the store, determining if one or several doctors make up a disproportionate share of the dispensing at the pharmacy, and contacting pharmacy operations to verify the information received from the store*

[146] CVS-MDLT1-000010205-000010208.

[147] See email string attaching document and corrections made which created another revision number 3, but that revision number 3 is dated 1/21/13. (See CVS MDLT1-000025365-000025369).

[148] CVS-MDLT1-0000010201–000010212.

[149] CVS-MDLT1-0000030545–000030548.

[150] CVS-MDLT1-000010205 -000010208.

[151] CVS-MDLT1-000030546-000030548.

> *and to obtain any relevant information they may have about prescriber, nearby clinics, changes in the competitive landscape, or changes in the circumstances such as a new emergency room or clinic opening nearby that might impart the ordering history. If the SOM Manager agrees that order is an order of interest, the Distribution Center will be contacted, both by email and telephone, by the SOM Manager to place a Hold on the drug family in question on the order of interest and the SOM Manager will communicate to the Distribution Center each day to hold future orders for the store in question until the order of interest is verified. Once the order of interest is placed on hold, the process enters phase two, Review and Research.*

In Document B the second paragraph of the policy contains the following language:

> *Once an order of interest is identified, the SOM Analyst will complete all the necessary due diligence, according to the SOM Due Diligence SOP, and the SOM Manager will be notified to review the order. Due diligence will include, but is not limited to: contacting the Pharmacist, reviewing ordering date, etc. If the SOM Manager agrees that the order is an order of interest, the Distribution Center will be contacted, both by email and telephone, by the SOM Analyst to place a Hold on the drug family in question on the order of interest. Also, the SOM Analyst will communicate to the Distribution Center each day to hold future orders until the order of interest is verified. Once the order of interest is placed on hold, the process enters phase two, Review and Research.*

The language in Document A provides a comprehensive description of the type of due diligence investigation required to review an order identified by the CVS system as potential suspicious orders when compared with Document B. The differences in language have a potential to render a different decision in regards to the effectiveness of the due diligence investigation. Document B contains the additional statement, "according to the SOM Due Diligence SOP." Document B does not specifically identify where to find the SOM Due Diligence SOP. There is no mention of due diligence investigations in the Controlled Drug – DEA Standard Operating Procedures Manual and this is supposed to be the single source document. [152]

Another significant difference was in regards to due diligence process. In Document A in the "Identify and Hold Section" of the policy the first paragraph contains the following language:

> *The purpose of the Identify and Hold phase is to identify potentially irregular orders and place a Hold on those orders at the Distribution Center. All orders identified as potentially irregular are labeled "orders of interest" unless determined to be suspicious following the initial due diligence process. Orders of interest are identified by the SOM Analyst while reviewing the PSE Item Review*

[152] CVS-MDLT1-00008572-000008635.

> *Report (IRR}, the Control IRR, and/or the Florida 5000 Dose Report (FRR) or by warehouse employees reviewing or packing orders for distribution to CVS Stores.*

In Document B the language "or by warehouse employees reviewing or packing orders for distribution to CVS Stores" has been omitted.

Another significant change occurred on the first page in Section 1. – Purpose. The language in Document A is as follows:

> *To detail the three phase approach developed to effectively identify, review and stop potentially irregular orders of PSE or controlled substance drugs identified by the CVS/Caremark Suspicious Order Monitoring (SOM) process, as well as report orders that are deemed to be suspicious.*

The language in Document B for the same section as listed above is as follows:

> *To detail the 3 phase approach developed to effectively review and stop a potentially suspicious order of PSE or Control drug identified by the CVS/Caremark Suspicious Order Monitoring (SOM) process, as well as report orders that are deemed to be suspicious.*

In Document B the word "identify" no longer appears. Further, Document A uses the term "irregular orders" which is changed to "suspicious order" in Document B. The change of these words become more impactful when the use of the term "order of interest" is used in the letter to Mr. Gillen. This change in terminology regarding this area may cause the potential for the reader to draw a different conclusion at which point the order should be reported as suspicious to the DEA. In August, 2013, CVS created "Work Instructions for Suspicious Order Monitoring" [153] and a "DCHuddle Guide."[154] Both of these documents inform employees of CVS's desire to detect and block suspicious orders of controlled substances and other listed chemicals, and they both beg the question of what CVS was doing until August of 2013. Indeed, although CVS claims that its SOM process since at least 2006 relied on Pickers and Packers to detect and stop suspicious orders, the Huddle Guide appears to be the first written instructions addressing the SOM issue that CVS ever provided to Pickers and Packers.

Other policies and procedures that CVS produced appear to be different versions of documents discussed above, or, in some cases, documents that relate to the new SOM system CVS gradually rolled out in 2014 (the first distribution center going live on March 2, 2014). Due to the limited amount of time that CVS distributed opioids after the introduction of the new SOM system, I have not been asked to opine on this system. I am, however, aware of some of the issues that were raised internally regarding the effectiveness of the new system.[155]

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[153] CVS-MDLT1-000000299–00000303.

[154] CVS-MDLT1-00003028-00003032.

[155] Schiavo Depo., 374:23-385:22.

3. Enforcement Actions:

In August, 2013 the DEA initiated a regulatory investigation at the CVS Distribution Center in Indiana.[156] After the investigation and after the DEA had outlined some concerns with what it found at CVS, Mark Nicastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. CVS cited the robust "due diligence processes in our pharmacy operations group, which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores" as the "primary contributor to the limited number of suspicious orders identified through our distributor SOM process."[157] The sufficiency of the pharmacy level due diligence component of the CVS SOM program is belied by numerous DEA actions against CVS for the significant due diligence failures in its pharmacy operation, including the following:

a. On October 13, 2010, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA to resolve the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy distribution center in Southern California. The CVS Distribution Center in La Habra, California, was in a position to monitor and report excessive PSE sales to the DEA, but failed to do so, in violation of 21 U.S.C. Sec. 830(b) and 21 C.F.R. Sec. 1310.05(a)(1). CVS paid a penalty of $75,000,000 and forfeited $2.6 million in profits for a total payment of $77.6 million.[158]

b. On March 28, 2013, CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy L.L.C. entered into a Settlement Agreement with the United States and the DEA to resolve claims that CVS violated the CSA by: (1) filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS dispensing records including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions. CVS paid a fine of $11,000,000.[159]

c. On September 2, 2014, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA to resolve claims against CVS for filling (from April 1, 2012 to July 31, 2012) 153 prescriptions at eight (8) different pharmacies, written by

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[156] CVS-MDLT1-00008014–00008015.

[157] Nicastro Depo, 203-206; Ex. 42.

[158] *See* October 13, 2010 Non-Prosecution Agreement. *See also* https://www.justice.gov/archive/usao/cac/Pressroom/pr2010/148.html.

[159] CVS-MDLT1-000060822–000060829.

the same physician, during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a $1,912,500 fine.[160]

d. On May 12, 2015, CVS Health entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64." The Settlement also covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances" and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of $22,000,000.[161]

e. On August 7, 2015, CVS Health entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that between March 3, 2010 and August, 2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA numbers (knew or should have known in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions, in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners, in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a $450,000 fine.[162]

f. On December 31, 2015, the DEA issued a Letter of Admonition for violations in distributing HCPs at the CVS Indiana distribution center.[163] This DEA finding was the result of the 2013 investigation. The DEA found that CVS violated the Controlled Substances Act because of a:

> "[f]ailure to design and maintain a system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Title 21 United States Code (USC) 821, Title 21 USC 823(e)(1), and Title 21 Code of Federal Regulations (CFR) 1301.74(b) in violation of Title 21

[160] CVS-MDLT1-000060907–000060914.

[161] CVS-MDLT1-000060796–000060804.

[162] CVS-MDLT1-000060847–000060855.

[163] CVS-MDLT1-00008014–00008015.

USC 842(a)(5) in that CVS failed to detect orders that should have been identified as suspicious for retail locations in Vincennes and Kokomo, Indiana.[164]

g. On February 12, 2016, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA. In the Settlement, CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA…." CVS paid a fine of $8,000,000.[165]

h. On June 30, 2016, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that between 2011 and 2014 CVS pharmacies in Massachusetts had filled hundreds (523) of forged opioid prescriptions. CVS entered into a multi-year compliance agreement and paid a fine of $3,500,000.[166]

i. On July 5, 2017, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA as a result of a DEA investigation showing "an increase in the number of thefts and unexplained losses of Hydrocodone…" at numerous Eastern District of California CVS retail stores. The Settlement resolved claims for the following misconduct: 1) failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances" (*see* 21 C.F.R. §1301.71(a)) and failure to notify the DEA of certain thefts or significant losses of controlled substances within one business day of the discovery (*see* 21 C.F.R. §1301.74(c)); 2) failure to maintain Schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv)); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms (21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their recordkeeping obligations, but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of $5,000,000.[167]

[164] CVS-MDLT1-00008014–00008015.

[165] CVS-MDLT1-000060805–00060811.

[166] CVS-MDLT1-000060872-00060906.

[167] CVS-MDLT1 000060856-000060871.

4. Suspicious Orders Reported In CT3 Jurisdictions:[168]

2006: 0

2007: 0

2008: 0

2009: 0

2010: 0

2011: 0

2012: 0

2013: 0

2014: 0

5. Opinions Related to CVS:

a. **CVS failed to *maintain effective control* against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].**

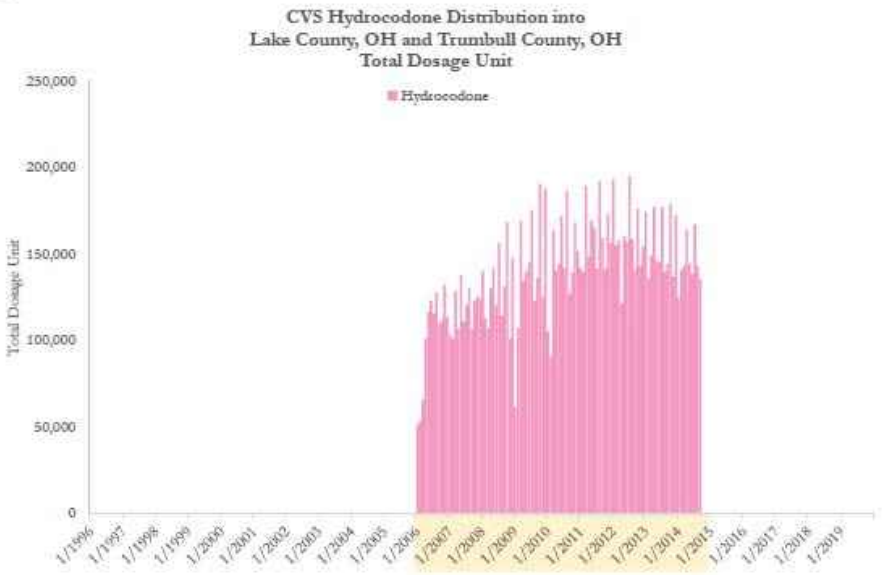
The graphs below demonstrate a clear escalation of prescription hydrocodone by CVS into Lake and Trumbull Counties in dosage units, MME, and base weight.[169]

[168] CVS has indicated that it has no evidence that it reported any suspicious orders arising out of CT3. In discovery, CVS stated that "based on its investigation to date, CVS did not centrally track or maintain suspicious order reports that it filed with DEA prior to the implementation of its current corporate suspicious order monitoring system in 2014, and CVS stopped distributing Opioids by October 2014. Pursuant to Rule 33(d) of the Federal Rules, CVS will produce, to the extent they can be found after a reasonable search, suspicious order reports filed with DEA for orders of Opioids that CVS distribution centers received from CVS Pharmacy retail stores. Examples of these documents include CVS-MDLT3-000067776, CVSMDLT3-000067778, CVS-MDLT3-000067780, CVS-MDLT3-000067782, CVS-MDLT3- 000067783, CVS-MDLT3-000067785, and CVS-MDLT3-000067786. I have been informed that none of the suspicious order reports listed by CVS are for CT3 stores.

See Amended Response to Interrogatory No. 3 at CVS'S AMENDED OBJECTIONSAND RESPONSES TO INTERROGATORIES NOS. 3, 4, 8, 9, 10 AND 11 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS.

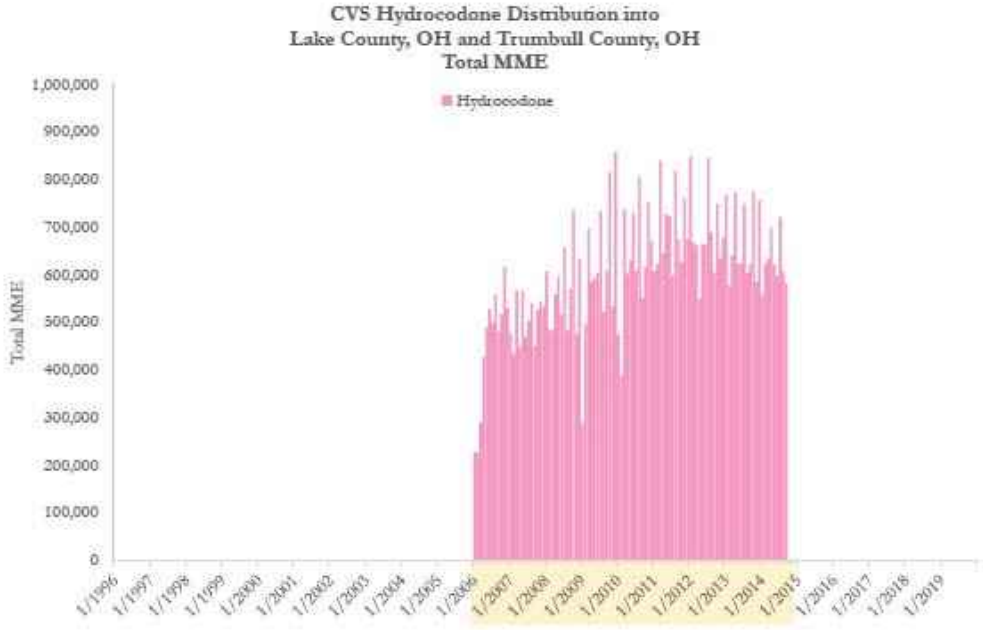
[169] Report of McCann, Appendix 9.

Region: Lake County, OH and Trumbull County, OH
Time: 1/2006 - 12/2014
Seller: CVS
Buyer: All Buyers
Drug: Hydrocodone

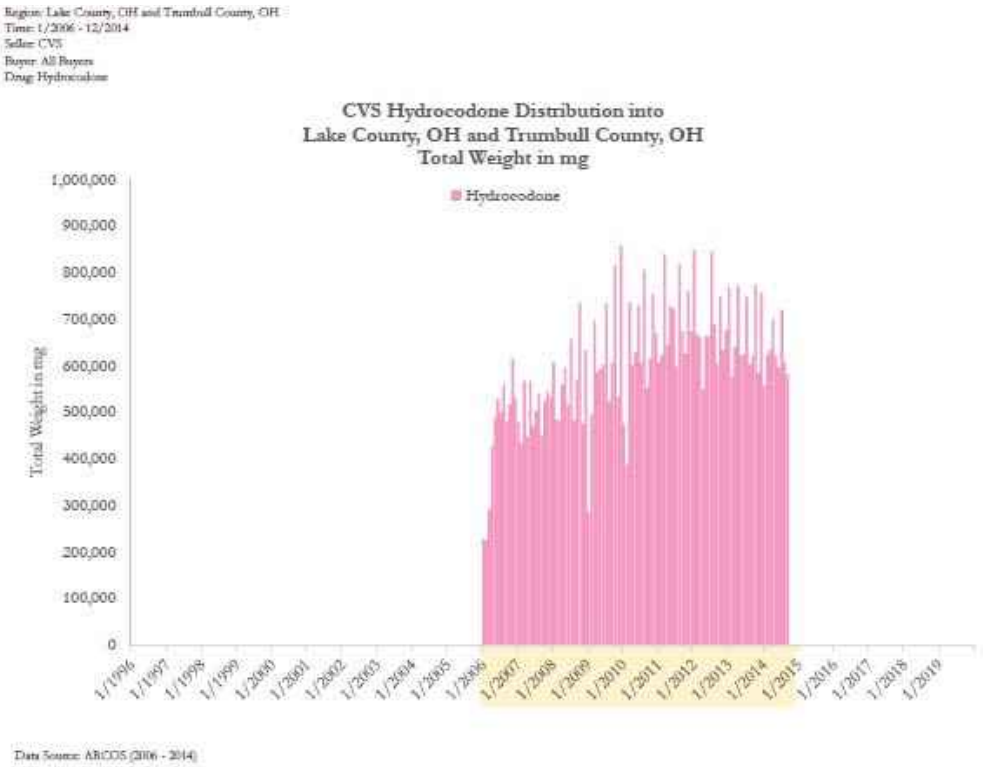


Data Source: ARCOS (2006 - 2014)

Region: Lake County, OH and Trumbull County, OH
Time: 1/2006 - 12/2014
Seller: CVS
Buyer: All Buyers
Drug: Hydrocodone



Data Source: ARCOS (2006 - 2014)



In my opinion the massive increase in prescription opioids without sufficient due diligence documented is indicative of a failure to maintain effective control.

b. **CVS failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the *security requirement* set forth in 21 C.F.R. § 1301.74(b).**

1) **Period #1: 2006 – early to mid- 2009**

From 2006 to early to mid-2009, the CVS SOM program consisted of Pickers and Packers and PDMR ("Viper") Reports.

Pickers and Packers were stationed in the controlled substance cage within the distribution center who would pick and pack controlled substance orders. The Pickers and Packers would identify orders that they believed were simply too large and would notify the Rx Inventory Control manager of the order. Ms. Wilson, a Picker and Packer since 1996, testified that she was guided by a "gut feeling" and then later testified that she used a crude rule of thumb that she learned in 1996 that, according to her, never changed throughout the entire period that CVS distributed HCPs.[170] The evidence indicates that the first formal written policy for the Pickers and Packers was introduced in August, 2013 with two documents: 1) "Work Instructions for Suspicious Order

[170] Wilson Depo., 62:8 – 64:6.

Monitoring" [171] and 2) "DC Huddle Guide."[172] Regardless of the rule used by the Pickers and Packers, the evidence demonstrates that essentially no orders were ever identified by the Pickers and Packers as potentially suspicious and needing investigation. For the Indiana distribution center during the period from 2006 through 2014, Sherri Hinkle was the Rx Inventory Control person that the Pickers and Packers would notify if they believed an order merited investigation.[173] Ms. Hinkle testified that she would be notified and investigate approximately one control drug substance order every six months.[174]

Similarly, the Viper report was not an effective SOM process. CVS's own witnesses testified that this report was not a report to determine suspicious orders: "But the point of this was not to produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA."[175] Rather, the Viper Report was an aggregate report that showed shipping versus dispensing to determine whether there was a theft of product.[176] [177]

2) **Period #2 Early to Mid-2009 until March 2014**

(a) Item Review Reports[178]

In 2007 CVS hired Buzzeo to help create DEA control drug standard operating procedures. This engagement lead to the manuals identified above as the "CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manual." As part of the engagement, in late 2008-early 2009, Buzzeo delivered to CVS an "SOM model … designed to 'pend' an order which may be classified as a 'suspicious' order for DEA reporting purposes."[179] The SOM model consisted of complex multiple logistic regression algorithms and was designed to pend any order with a score of .15 or higher. The IRR was a print-out that consisted of all controlled drug orders for that day that were identified as potentially suspicious by the SOM algorithm. This was a daily report that was run five days per week. As is described in the Due Diligence Conducted section

[171] CVS-MDLT1-000000299–00000303.

[172] CVS-MDLT1-00003028-00003032.

[173] Hinkle Depo., 14:5-15:22; 65:22-66:15; Wilson Depo., 40:21-42:1.

[174] Hinkle Depo., 83:23-86:1.

[175] Vernazza Depo., 191:18–21.

[176] Burtner Depo., 384:12–21.

[177] Dugger Depo., 104:12–22.

[178] During this period the IRR was the primary SOM process used by CVS. However, CVS also continued to use the Pickers and Packers and PDMR Viper reports in conjunction with the IRR.

[179] *See* Cegedim Dendrite Compliance Solutions Powered by BuzzeoPDMA "Descriptive Over Document: Cegedim Dendrice Suspicious Order Monitoring (SOM) Model" Version 1.0 – December 2008. CVSMDLT1-000123386–000123392).

below, CVS only performed due diligence on a small percentage of the orders identified in the IRR as potentially suspicious.

The IRRs had some specific problems that fit within the time periods below, but it also had one overarching issue that continued from mid-2009 until March, 2014 – when performing the calculation of whether the order was suspicious, the IRRs did not consider orders delivered to CVS pharmacies by outside vendors.[180] CVS had full access to every order its pharmacies placed to outside vendors but did not incorporate this information in its SOM system. Maintenance of effective controls requires CVS to utilize all relevant transaction information. Not surprisingly, the VIPER reports which are used as inventory tools and to gauge whether there is a loss of product from theft automatically incorporates outside vendor information. [181]

The outside vendor issue was not rectified until the new AGI SOM program was implemented in 2014. As late as January of 2013, CVS was analyzing the potential risks of not tracking orders that its pharmacies placed to outside vendors and concluded that it needed to due to the "DEA 'Know Your Customer' requirements."[182] CVS recognized that in order for the "dispensing data in the algorithm to be useful, we must account for all controlled substances ordered."[183] In fact, a CVS pharmacy lost 68,000 hydrocodone pills and then refilled its hydrocodone supply by calling outside vendors instead of placing orders through the CVS distribution centers.[184] According to CVS, in the event that CVS detected an order to an outside vendor which CVS identified "as an order deviating from normal size, frequency, and/or buying pattern and deemed to not be for legitimate purposes or are at risk of being diverted [those orders] are **not** required to be reported to the DEA."[185] This approach fails to maintain effective controls to prevent diversion.

(b) Early to Mid-2009 through March, 2011

(i) Changing the Algorithm Triggering Score

From early to mid-2009 through March, 2011, the IRR (for the entire country) was being reviewed by Henry "John" Mortelliti. Mortelliti was the first individual to begin review of the new IRR and he worked in loss prevention at the Lumberton distribution center in New Jersey. The SOM algorithm delivered in December, 2008 and implemented in early 2009 was designed to pend an order with a score of 0.15 or higher. In July, 2009 CVS reported to Buzzeo that the SOM model

[180] Burtner Depo., 284:21-285-20.

[181] Burtner Depo., 382:20-387:17.

[182] CVS-MDLT1-000103328, at 28.

[183] CVS-MDLT1-000103328.

[184] CVS-MDLT1-000103327.

[185] CVS-MDLT1-000078060-000078069, at 78068 (emphasis added).

was pending a large number of orders that CVS believed were "not suspicious on their face" and it requested that the model be changed. As a result, revised coefficients for the algorithm were delivered to CVS on August 27, 2009 and the pend score of .15 remained the same.[186] [187]. Between June, 2010 and August, 2010 Mortelliti adjusted the IRR pend score from .15 to .65.[188] On February 8, 2011 a completely retuned SOM algorithm was delivered to CVS with another set of co-efficients. The February, 2011 changes returned the pend score to .15.[189] However, a review of IRRs from February and March of 2011 shows that the pend score was .65. In fact, an IRR from as early as February 20, 2011, nine days after the consultant returned the model and returned the pend score to .15, demonstrates that the score at that point was already returned by CVS to .65.[190] Further, I have not seen documentary evidence to indicate why, after the model was retuned by the consultants and the pend score returned to .15, CVS again changed the pend score to .65.

(ii) All Flagged HCP Orders That Appear On The IRR Are Sent Out To Analysts For Additional Specialized Investigation

Mortelliti testified that while he was reviewing the IRR, every HCP order that appeared on the IRR was referred out for additional investigation which he believed was necessary.[191] Although Mortelliti testified that he felt it was necessary for all HCP flagged orders to be sent out for additional investigation, he did not know what due diligence was actually performed. It is my opinion that all HCP orders that were flagged on the IRR merited additional investigation beyond just reviewing the information on the IRR. Evidence exists that does not support Mortelliti's statement that all orders were sent out for investigation. Mortelliti testified that he would contact the loss prevention manager and the pharmacy manager of the distribution centers to freeze all orders that were flagged on the IRR.[192] However, Dugger, the Indiana loss prevention manager, told the DEA that he never received a call from Mortelliti about the IRR.[193] Mortelli was questioned during his deposition as to whether he was able to find documentation that supported his position that he sent all IRR flagged orders of HCP out for additional investigation. He testified that he tried to find documents that supported his story that he sent these flagged orders out for additional investigation but he was unable to find any supporting documents.[194]

(iii) Algorithm Not Functioning Correctly – Loses Historical Data – Active Ingredient

[186] CVS-MDLT1-000109623-000109625.

[187] CVS-MDLT1-00114642-00114652.

[188] Mortelliti Depo. Exs. 612, 614, 615.

[189] CVS-MDLT1-24494; 24495-24499; Hinkle Depo., pp. 194-214.

[190] CVS-MDLT1-000100851-000100864.

[191] Mortelliti Depo., 367:1–14.

[192] Mortelliti Depo., 57:16 – 58:12.

[193] Mortelliti Depo., 58:17 – 62:18; Exh. 135.

[194] Mortelliti Depo., 220:7 – 221:22.

In October of 2010 it was discovered that the algorithm was not functioning properly. Because the algorithm monitored orders by drug and not active ingredient, any change in how the drug was identified would cause the historical data to be lost. In a business description document requesting resources to change the model, Mortelliti wrote in October of 2010, that the algorithm model lost historical data and caused CVS to not be compliant with DEA expectations.[195] The loss of the historical data caused the algorithm to not function properly. Although it is unclear when the model was fixed, a business request update of April 25, 2011 indicated that the problem was still not fixed and it had a finish date of December 31, 2011.[196]

(c) March/April, 2011 to December, 2013

In March/April, 2011 CVS moved the IRR review process to the Knoxville, Tennessee distribution center. At this point, the active ingredient issue was still not fixed and the IRRs were still missing historical data. From March, 2011 until early 2012, the IRR review for the entire country was centralized in Knoxville. In early 2012, Aaron Burtner began reviewing IRRs at the Indiana distribution center.[197] During this period, the evidence indicates that the IRRs would consist of hundreds of flagged orders with some IRRs having over 1,000 orders. All orders listed on the IRR were identified by the computer algorithm as potentially suspicious and should have had additional investigation. The evidence indicates that during this period, very few orders that were identified on the IRR as potentially suspicious were investigated beyond the IRR.

6. Due Diligence Conducted

Due diligence, as it relates to CVS's SOM program, can be broken down into two distinct subparts: i) What tools were available to conduct due diligence; and ii) What due diligence was actually performed based on the evidence produced by CVS. CVS might claim that reviewing the information contained within the four corners of the IRR constitutes due diligence, but little information exists on the IRR that is probative of why an order is suspicious and represents a threat of diversion. The CVS SOM program was dependent upon all flagged orders receiving a comprehensive due diligence investigation. This was acknowledged by Mortelliti when he testified that he referred all HCP flagged orders out for additional investigation. The evidence demonstrates that CVS conducted very little effective due diligence.

a. What tools were available to conduct due diligence:

1. Viper Report It appears that before 2012, the Viper report was the only due diligence tool available. As outlined above, Viper was really just an inventory control, theft

[195] Mortelliti Depo., 129:11 – 131:11, Ex, 16; Vernazza Depo., 400 – 455.

[196] Mortelliti Depo., 177:9 – 186:2.

[197] In September, 2012 the IRR review is centralized again and now the entire country is being reviewed at the Indiana distribution center.

detection system and was not designed or operated to "produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA."[198]

2. Microstrategy Microstrategy was implemented as a SOM tool in February, 2012.[199] This database was the primary SOM tool an analyst could use if an investigation of an order beyond the IRR was done. Microstrategy provided an analyst with the information necessary to do appropriate due diligence: patient ID number, if a doctor is prescribing an inordinate amount, how the drugs were paid for, distance patients traveled to fill the prescriptions, quantity dispensed, dispensing data, information on the pharmacy, information on the patient, [200] and outside vendor deliveries of the same drugs to the stores. [201]

3. Store metrics In December, 2012, CVS introduced a new tool for due diligence called Store Metrics that produced a report called "Store Statistics for SOM Order Review." Store Metrics contained much of the same information (top doctors, top patients, volume, distance traveled, patient population, payment method)[202] but formatted into an easily readable report. The Store Metrics report was the primary tool for doing investigations, but the report used stale data that by July, 2013 was over one year old and made the report "irrelevant and pointless."[203]

b. **What due diligence was actually performed based on the available evidence:**

All of the evidence indicates that CVS performed due diligence on very few orders that were flagged by the IRR system. Mortelliti testified that while he was reviewing IRRs from mid-2009 until March of 2011 he sent every flagged orders of HCP out for additional investigation, but as addressed above and below that is not supported by the evidence. Further, the evidence affirmatively demonstrates that from January, 2011 until the new SOM system was implemented in March, 2014, very few of the national orders that flagged on the IRR as suspicious were ever investigated. This is established by 1) the IRR recaps that list the few flagged orders that received a due diligence investigation; 2) an email dated February 12, 2013 from Aaron Burtner to Crystal Pike at Analysis Group that attaches all orders flagged for additional review; 3) the time studies that demonstrate how few orders were actually investigated; and 4) the testimony of Gary Millikan who indicated that he investigated 5% or less of the IRR flagged orders; and 5) the testimony of Shauna Helfrich and Kelly Baker who both indicated that they did not investigate all of the flagged orders and they had no idea how many they would actually investigate.

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[198] Vernazza Depo., 191:18-21.

[199] Burtner Depo., 379:4-13.

[200] Burtner Depo., 385: 6–18; 396:23–397:17; Helfrich Depo., 18:4–19:8; 176:3–12.

[201] Burtner Depo., 284-6: 285:9.

[202] Burtner Depo., 311:2-23.

[203] Baker Depo., 259:16–262:19; Ex. 27; Ex. 29.

1) IRR Recaps:

According to CVS policy and testimony, anytime an order received due diligence beyond simply reviewing the IRR, that review was documented on the IRR Recap.[204] Review of the IRR Recap Reports appears to show that no CT3 HCP orders received additional investigation. The IRR Recap Report from January, 2011 to June, 2012 shows that no HCP order placed by a pharmacy in CT3 was investigated.[205] The IRR Recap Report from February 6, 2013 to December 30, 2013 shows that no HCP order placed by a pharmacy in CT3 was investigated.[206] Additionally, an IRR Recap from January 2, 2014 to February 11, 2014 shows that no CT3 HCP orders were investigated during this time period.[207]

2) Email Dated February 12, 2013 From Aaron Burtner to Crystal Pike at Analysis Group

On February 12, 2013 Aaron Burtner sent an email and attachments to Crystal Pike at Analysis Group with a CC to various Analysis Group (AGI) and CVS employees such as Pam Hinkle and Dean Vanelli, among others.[208] During this time period AGI was updating the current SOM system and designing the new SOM system. The email from Mr. Burtner reads in part as follows: "Attached are all order flagged for additional review from Dec 2010 – Present. There are two tabs; 1 for Control drugs and 1 for PSE/EPH. I have been informed that a random spot-check of the orders flagged for additional review corresponds with the orders shown on the IRR Recaps. I have also been informed that a review of the attachment indicates that no CT3 HCP orders were flagged for additional review from February, 2011 to February 11, 2013.[209]

3) Time Studies:

Mr. Burtner, who began reviewing IRRs in February, 2012 and was subsequently named the SOM Manager, created various time studies as part of his job. The time studies were intended to track a typical day. During the time Burtner created the time studies he was reviewing the IRR for half the country – five distribution centers. Over twelve days in 2012, the time studies indicate Burtner performed an investigation beyond the IRR on zero (0) orders on eight (8) separate days; one (1) order on two (2) separate days; two (2) orders on one (1) day; and three (3) orders on one (1) day. In other words, regardless of the number of orders flagged, for one half of the country

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[204] Burtner Depo., 404: 24–405:10; 474:23–475:8. Hinkle Depo., 130:8 - 131:1.

[205] CVS-NYMDL-000008036.

[206] CVS-MDLT1-000010268 – 000010521. An order for Tramadol ER 300 mg for Store 3304 on May, 20, 2013 does show up on an IRR Recap. CVS-FLAG-000021160.

[207] CVS_MDLT1-000010235-00001067.

[208] SA-AGI – 000068524. Attachment found at SA-AGI – 000068525.

[209] SA-AGI – 000068525.

over a period covering twelve days ranging from June 14, 2012 to September 6, 2012, CVS investigated a total of seven control substance orders.[210]

4) Less Than 5%:

Gary Millikan was the operations manager at the Indiana distribution center from 1998 until 2010, and the production manager until he retired in June, 2012. He also was the Indiana distribution center DEA Compliance Coordinator from 2006 through his retirement in June, 2012.[211] Because the distribution center was so short-staffed in the SOM department, he came back to work part-time in August, 2013 and he started reviewing IRRs. Mr. Millikan admitted during his deposition that he did due diligence on less than 5% of the suspicious orders flagged on the IRR.[212]

In practice, CVS had no idea how few orders were actually investigated. Shauna Helfrich, an IRR analyst, testified that she does not remember how many flagged orders on an IRR she did additional due diligence on. Despite repeated questions on her due diligence efforts, Ms. Helfrich was not able to even estimate or give a percentage of how many flagged orders on which she did due diligence. She had absolutely no memory or idea of the orders on which she did due diligence.[213] Kelly Baker, another IRR analyst, also could not remember how many flagged orders on an IRR he did due diligence or a deep dive on. He merely remembers one example of a deep dive that he did and that is it. Furthermore, Mr. Baker did not dispute Gary Millikan's testimony that he did a deep dive on about five percent of the orders on an IRR.[214]

It is my opinion that, at a minimum, all orders that flagged on the IRR should have received additional investigation. This would include all orders that flagged on the IRR as a result of violating CVS's Maximum Cutoff Volume and Maximum Cutoff Ratio; two thresholds that were established in October, 2012.[215] I agree with Mr. Mortelliti's testimony that all flagged orders of HCP needed to be referred out for additional investigation.[216] Additional investigation could include review of patient profiles such as the age, distance traveled, and method of payment; review of ratios of HCP purchases to other controlled substances; review of other drugs purchased that consist of a drug cocktail; review or comparison to like stores; review of prescribing physician

[210] Burtner Depo., 340–371; 505; Ex. 500.

[211] Millikan Depo., 32:20 – 33:11.

[212] Millikan Depo., 213:9 – 214:12.

[213] Helfrich Depo., 105:5-107:24.

[214] Baker Depo., 102:9-103:6; 165:14-166:22.

[215] CVS-MDLT1-00055836-00055838.

[216] Mortelliti Depo., 367:4-22; 368:22-369:2.

profiles; and total amount of a drug purchased by the pharmacy. As is clear, none of this information is shown on the IRR.[217]

The implications of the failure to perform additional investigation on orders flagged on the IRR cannot be overstated. As referenced above, no HCP orders were investigated in CT3. I have been informed that evidence exists to demonstrate that over 30 HCP CT3 orders flagged on the IRR and it appears that none were investigated by CVS. The number of IRR flags must be evaluated with the understanding that CVS had also artificially reduced the number of orders flagging by increasing the pend score from .15 to .65.

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by CVS has been inadequate. While CVS has employed different due diligence programs over the years, a review of those programs in practice make clear that for all practical purposes, CVS's due diligence efforts have fallen short of what is required.

7. **Reporting Requirement**.

CVS timely reported zero suspicious orders from 2006 to September 30, 2014. Further, using any of the methodologies as described in the Expert Report of Craig McCann, it is apparent CVS failed to report thousands of suspicious orders arising out of Lake County and Trumbull County.[218]

8. **Shipping Requirement.**

CVS claims that when it "determines that an order for a controlled substance is suspicious, its policy is and has been to decline to ship the order and to report the order to the DEA."[219]

B. Walgreens Boots Alliance

Distribution Centers:

During the relevant time period Walgreens Boots Alliance, Inc. ("Walgreens") had 13 Distribution Centers ("DCs") that handled controlled substances. Three of those DCs handled schedule 2 controlled substances (Jupiter, Florida; Perrysburg, Ohio; and Woodland,

[217] Millikan Depo., 230:24-232:7. Additionally, total purchased is not shown on the IRR since the IRR does not include outside vendor orders.

[218] *See* Section IV, "Identifying Suspicious Orders Distributed in CT3."

[219] *CVS'S WRITTEN RESPONSES TO TOPICS 8, 9, 12, 13 AND 14 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6), Response No. 14.*

California).[220] According to Walgreens Transactional Data, Walgreens distributed prescription opioids to the CT3 jurisdictions through at least five of its Distribution Centers:[221]

- Perrysburg, Ohio Distribution Center (DEA # RW0294493) from at least May 2003 through March 2013;
- Mt. Vernon, Illinois Distribution Center from (DEA # RW0152467) February 2013 through April 2014;
- Jupiter, Florida Distribution Center (DEA # RW0277752) from at least September 2002 through January 2007;
- Bethlehem, Pennsylvania Distribution Center (DEA # RW0161872) from at least August 2002 through May 2003; and
- Windsor, Wisconsin Distribution Center (DEA #PW0211158) (one shipment into CT3).[222]

Transactional Data:

Date range: 2006-2014 (ARCOS)

Volume:

Lake[223]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	7,141,000	87,402,068	58,268
Hydrocodone	6,161,370	24,737,546	24,738

Trumbull[224]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	4,021,900	93,650,861	62,434
Hydrocodone	8,456,930	39,093,015	39,093

1. Court ordered SOMS Related Discovery Disclosure

- *Track One - Walgreen Co. And Walgreen Eastern Co.'s Second Amended Objections and Responses to Plaintiffs' First Set of Interrogatories (3/04/2019);*

[220] *See* WAGMDL00659801 at WAGMDL000659817. *See also* WAGFLDEA00000117 (listing all three CII facilities).

[221] *See* WAGMDL00293631; WAGMDL00490979; WAGMDL00773926; ABDCMDL00170319; and MNK-T1_0005986422 at MNK-T1 0005986423.

[222] March 5, 2021, Walgreens' Third Supplemental Responses and Objections to Plaintiffs' (First) (Modified) (Combined) Track Three Interrogatories.

[223] Report of McCann, Appendix 8.

[224] *Id.*

- *Track One - Walgreen Co. and Walgreen Eastern Co's Second Supplemental Responses to Plaintiffs' "(First) Combined Discovery Requests" (2/19/2019);*

- *Track One - Walgreen Co. and Walgreen Eastern Co's Objections and Responses to Plaintiffs' First Notice of Deposition Pursuant to Rule 30(b)(6) Topic 1(O) and Second Notice of Deposition Pursuant to Rule 30(b)(6) Topics 2 (A)-(J), 9, 10, 11, 13, 14 and 15 (1/17/2019);*

- *Track One B - Walgreen Co. And Walgreen Eastern Co.'s Response to Plaintiffs "Initial Disclosures" Requests (12/31/2019)*

- *Track One B - Walgreen Co. And Walgreen Eastern Co.'s Supplemental Responses to Plaintiffs (First) Combined Discovery Requests to Dispensers (2/21/2020)*

- *Track Three – Walgreens Boots Alliance, Walgreen Co., and Walgreen Eastern Co.'s Written Responses to Certain of the Plaintiffs [Data] 30b6 Topics (2/15/2021)*

- *Track Three – Walgreens Boots Alliance, Walgreen Co., and Walgreen Eastern Co.'s Written Responses to Certain of the Plaintiffs [General] 30b6 Topics (2/26/2021)*

- *Track Three – Walgreens Boots Alliance, Walgreen Co., and Walgreen Eastern Co.'s Third Supplemental Responses and Objections to Plaintiffs' (First) (Modified) (Combined) Track Three Interrogatories (March 5, 2021).*

2. SOMS Corporate Policy Disclosed:

Walgreens's various SOM Programs are described in my opinions, set forth below in other areas of this report.

3. Enforcement Actions:

In May 2006, the DEA sent Walgreens a Letter of Admonition citing Walgreens for recordkeeping inadequacies and security deficiencies at its Perrysburg Distribution Center. Specifically, the DEA found that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient."[225]

On April 7, 2011, Walgreens entered into a Settlement Agreement with the DEA regarding allegations of non-compliance with the Controlled Substance Act wherein Walgreens had agreed to "maintain a compliance program to detect and prevent diversion of controlled substances."[226]

[225] WAGMDL00709510.

[226] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387975.

In April 2012, the DEA served a Subpoena to one of Walgreens's Schedule 2 controlled substance distribution centers, the Jupiter Distribution Center, requesting, among other things, all controlled substance SOPs, communications about controlled substances, and customer due diligence files for 14 Walgreens stores, and also served a Warrant of Inspection on the Jupiter Distribution Center, authorizing seizure, among other things, all records related to distribution of controlled substances.[227]

After reviewing the materials provided by Walgreens in response to the April 2012 subpoenas, on September 13, 2012, the DEA issued an Order to Show Cause (OTCS) and Immediate Suspension of Registration (ISO) to Walgreens on the basis that the Jupiter Distribution Center constituted "an imminent danger to the public health and safety" and ordered that Jupiter controlled substance vault be sealed.[228] The DEA alleged that Walgreens's Jupiter DC failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies. Further, the DEA alleged that Walgreens's failure to sufficiently report suspicious orders was a systemic practice that resulted in at least tens of thousands of violations and allowed Walgreens' retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone.

In February 2013, after the DEA determined Perrysburg had not reported any suspicious orders to the DEA for the entirety of 2012,[229] the DEA issued Subpoenas and Warrants of Inspection on the Perrysburg Distribution Center similar to those issued to the Jupiter DC.[230] Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC.[231] Within weeks of receiving the six subpoenas and warrant, Walgreens decided to "discontinue distribution of controlled substances from the Perrysburg facility" in order to "eliminate any immediate need for further DEA administrative action" regarding the Perrysburg facility.[232] In May 2013, "based on the violations discovered as a result" of the Perrysburg warrant, the DEA increased the classification of the Perrysburg investigation from a "regulatory investigation" to a "complaint investigation."[233]

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[227] WAGMDL00777158; CAH_MDL2804_01431074.

[228] *See* Settlement and Memorandum of Agreement between the Department of Justice, DEA, and Walgreens Co., with appendices (collectively, "Walgreens 2013 MOA") (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387654 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012), ["Jupiter Show Cause Order"]).

[229] DEA-T3CC-00014231

[230] WAGMDL00493697; WAGMDL00493694.

[231] WAGMDL00477975; WAGMDL00358471.

[232] WAGMDL00674280.

[233] DEA-T3CC-00014159

On June 11, 2013 Walgreens entered into a Settlement and Memorandum of Agreement ("MOA") with the DEA to resolve outstanding allegations involving the Walgreens Distribution Centers and pending actions concerning six Walgreens retail pharmacies located in Florida. Walgreens agreed to pay $80 million in civil penalties, the largest settlement in DEA history at that time, to resolve the DEA's claims that Walgreens negligently allowed controlled substances, including oxycodone and other prescription painkillers, to be diverted into the black market.[234] In addition to the $80 million civil penalty, Walgreens agreed to surrender its Jupiter DC's registration to distribute or dispense controlled substances listed in Schedules II – V for two years from issuance of the Jupiter ISO, ending in 2014. As part of the MOA, Walgreens admitted that Walgreens's "suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007."[235]

4. **Suspicious Orders Reported In CT3 Jurisdictions:**

	Pre-Shipment Reporting	Post-Shipment Reporting
2006	None	Rigid Formula Reports (Customer Grouping Formula)
2007	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2008	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2009	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2010	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2011	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2012	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2013	None	None
2014	None	None
2015	None	None
2016	None	None
2017	None	None
2018	None	None

[234] *See* Walgreens 2013 MOA (WAGMDL00490963-978; WAGMDL00387975-982; WAGMDL00387653-974).

[235] Walgreens 2013 MOA (WAGMDL00490963-978; WAGMDL00387975-982; WAGMDL00387653-974) at WAGMDL00490964 (Page 2 of 349)

In its CT3 written discovery responses,[236] other than the Rigid Formula Reports, Walgreens only identified two "suspicious orders of opioids" by Ohio Walgreens stores from 2006-2014 that Walgreens reported to the DEA: a 12/09/2013 order for Hydrocodone by a Chillocothe, Ohio store,[237] and a 5/8/2014 order for suboxone by a Columbus, Ohio store.[238] In its responses, Walgreens also disclosed a spreadsheet listing 28 opioid orders for Ohio stores between May 2013 and January 2014, however, it is unclear from the face of the document whether these 28 Ohio orders were actually sent to the DEA.[239] Walgreens testified no due diligence was conducted on the orders listed in the Rigid Formula Reports.[240] As discussed below, Walgreens's internal audits further admit that, during the time Walgreens was utilizing the Rigid Formula Reports, there was "no monitoring process in place to stop a suspicious order to assess if the order is suspicious or not" and that Walgreens was "filling orders that have been deemed suspicious without performing any research to ascertain the legitimacy of the order"[241]

5. Opinions Related to Walgreens

a. Walgreens failed to *maintain effective control* against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].

The graphs below demonstrate a clear escalation of prescription oxycodone and hydrocodone by Walgreens into Lake and Trumbull Counties.[242]

[236] *See* Walgreens CT3 Second Supplemental Responses to Combined Discovery Requests at Request 3.

[237] SORS-000234

[238] SORS-000234

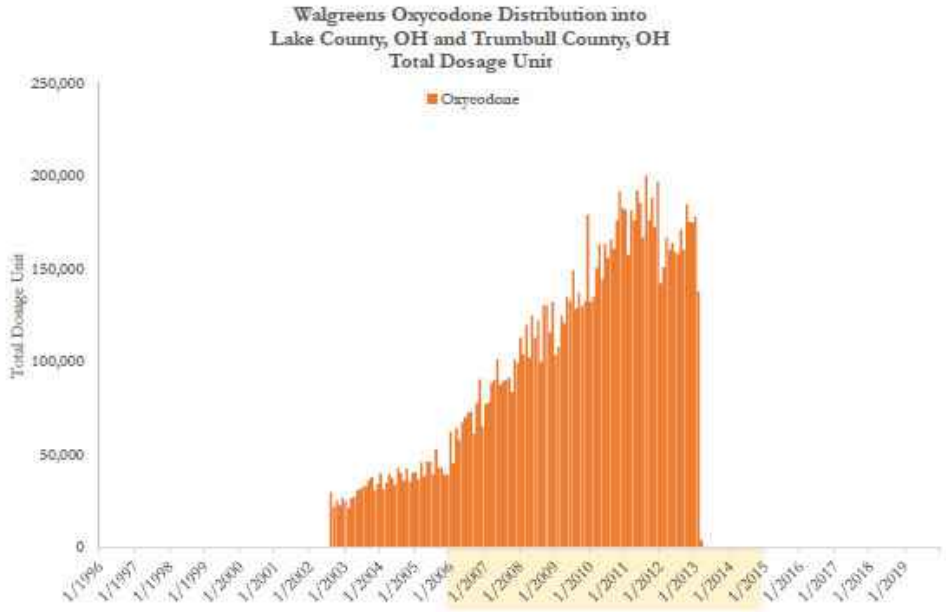
[239] WAGMDL00852039

[240] *See* Bratton Errata.

[241] WAGMDLPER00000001; WAGMDLPER00000020; WAGMDLPER00000313; WAGMDLPER00000350; WAGMDLPER00000353; WAGMDLPER00000379

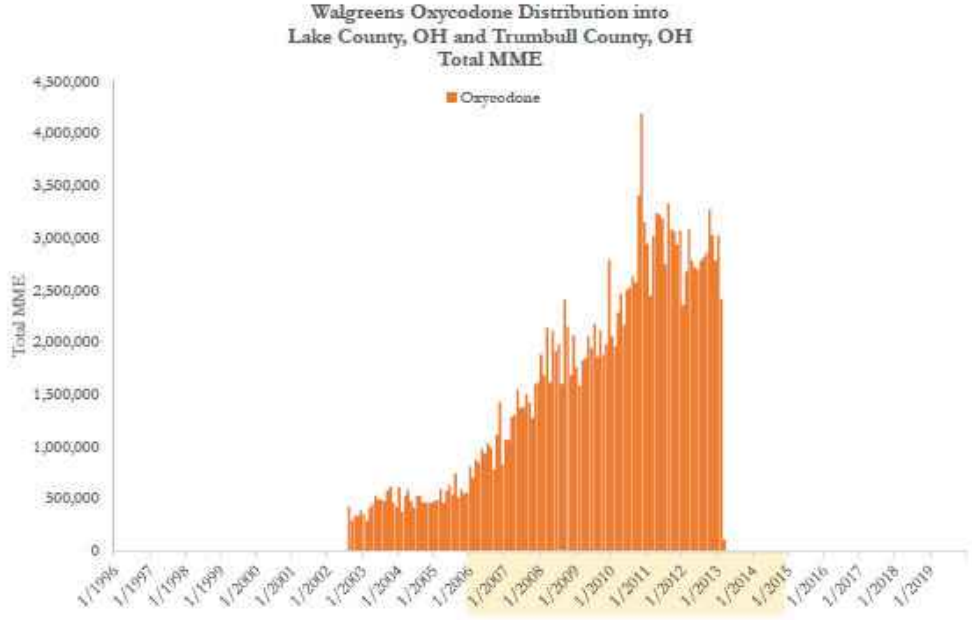
[242] Report of McCann, Appendix 9.

Region: Lake County, OH and Trumbull County, OH
Time: 8/2002 - 4/2014
Seller: Walgreens
Buyer: All Buyers
Drug: Oxycodone



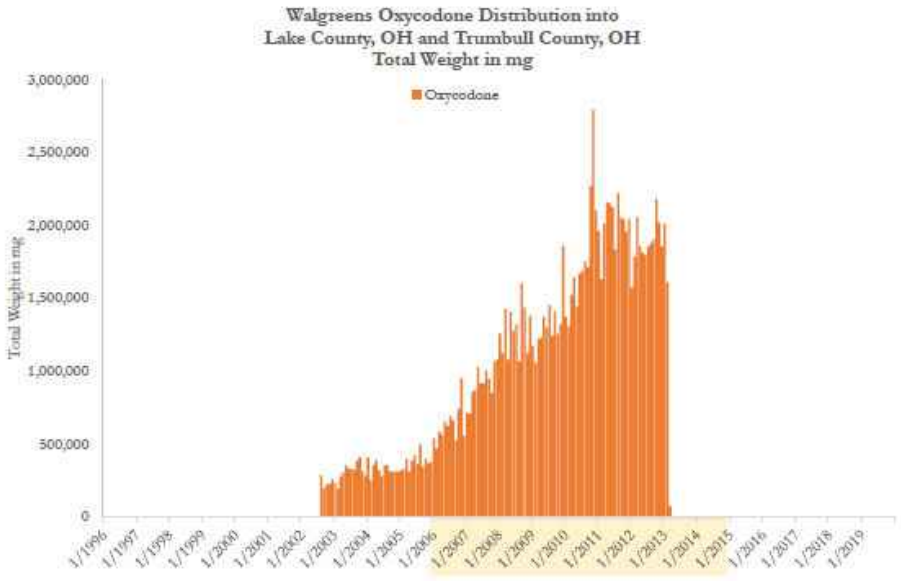
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 8/2002 - 4/2014
Seller: Walgreens
Buyer: All Buyers
Drug: Oxycodone



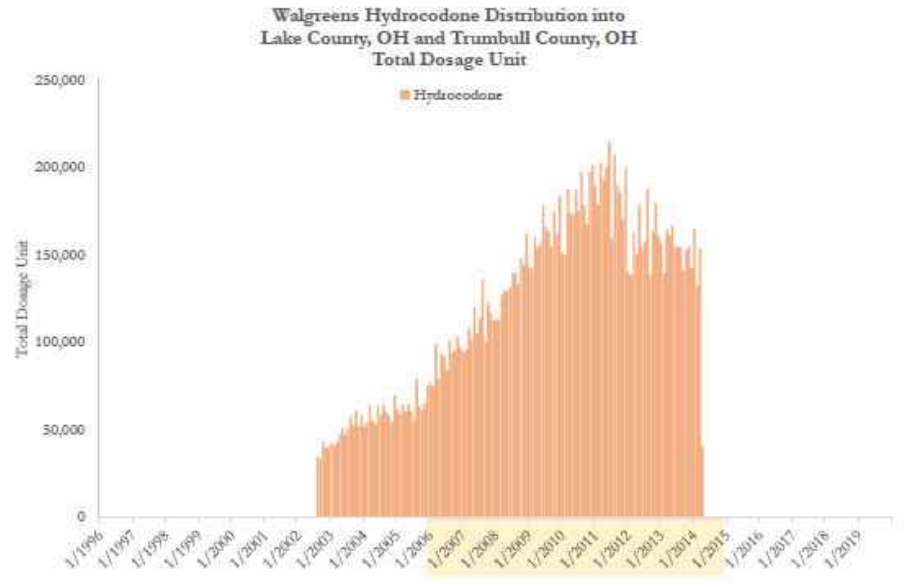
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 1/2002 - 4/2014
Seller: Walgreens
Buyer: All Buyers
Drug: Oxycodone

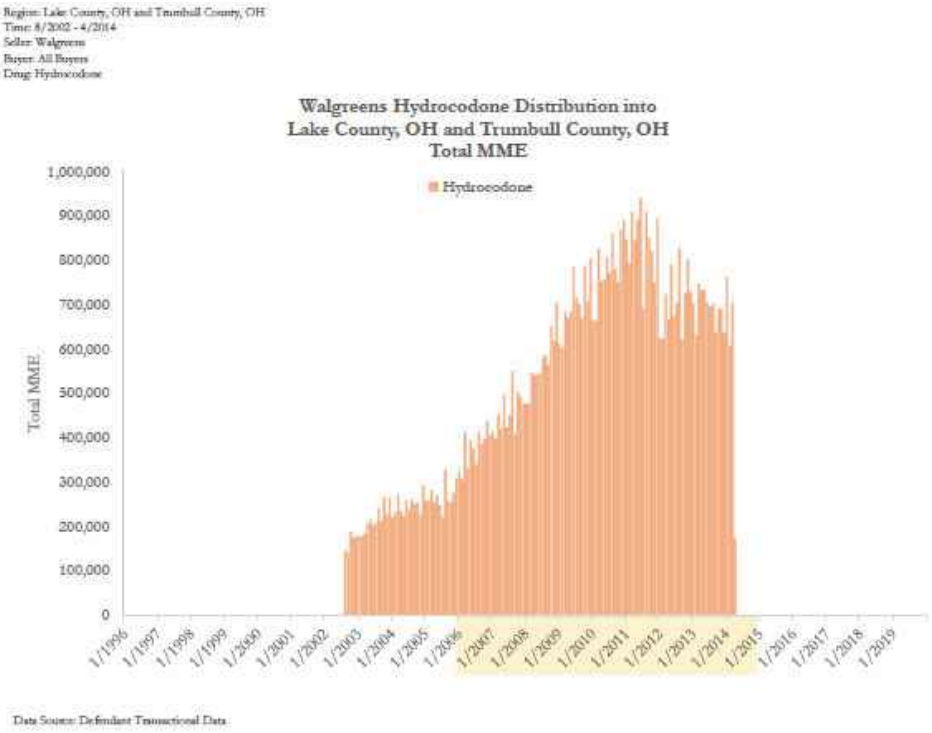


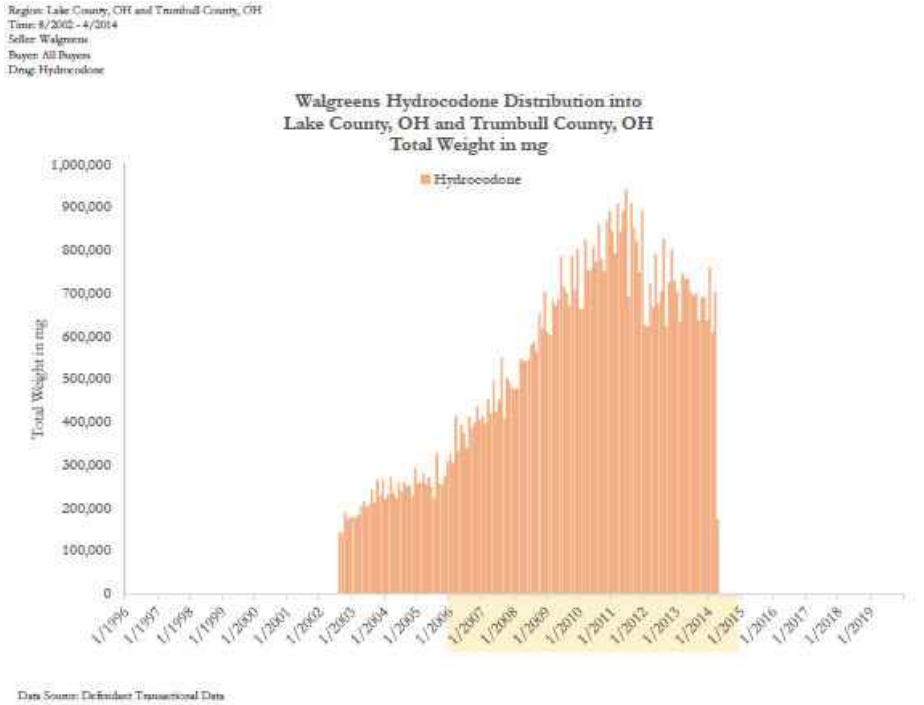
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 1/2002 - 4/2014
Seller: Walgreens
Buyer: All Buyers
Drug: Hydrocodone



Data Source: Defendant Transactional Data





In my opinion the massive increase in prescription opioids without sufficient due diligence documented is indicative of a failure to maintain effective control.

Walgreens also knew opioids it distributed in Florida were migrating into Ohio. Because Walgreens failed to maintain many pre-2012 documents outside of those produced to the DEA during the Jupiter DC investigation, many of the pre-2012 documents Walgreens produced relate to Walgreens distribution in Florida. This information is pertinent to CT3, however, because not only does the evidence show that Walgreens's distribution failures were "systemic", as noted by the DEA in the 2013 MOA, but the evidence further shows that Walgreens was aware that the high-volume Florida prescriptions were traveling out of state, including to Ohio. For example, Pharmacy managers in Florida alerted their supervisors and the distribution center that they were ordering 55+ bottles a week (where 30 bottles was an admitted red flag) and that many of the prescriptions were coming from out of state.[243] Walgreens was well familiar with the "Florida migration" phenomenon, in which prescription opioids were being dispensed in Florida and transported north to states including Ohio,[244] and knew that ''Interstate 95 has been renamed the Oxycodone Express because of the brisk travel of people from Kentucky, Tennessee, [and] Ohio to South Florida to obtain medications.''[245] When the DEA issued Orders to Show Cause to Walgreens's Jupiter Distribution Center and six Florida Walgreens pharmacies, the DEA specifically noted likely migration to Ohio.[246]

b. Walgreens failed to *design and operate a system to identify suspicious orders* of controlled substances in violation of the security requirement set forth in 21 C.F.R. § 1301.74(b).

Walgreens employed a number of limited and disjointed SOMS programs during overlapping time periods, none of which fulfilled Walgreens's duties under the CSA. Walgreens's documentation of many of these programs is minimal and, before 2011/2012, there is little evidence that Walgreens took adequate and effective steps to comply with the CSA's requirements. Walgreens alsoe allowed its pharmacies to order controlled substances through other distributors. This built-in work-around allowed the ineefective SOMs programs to be even less effective. Walgreens's failures to design and operate an effective SOM program are especially problematic because Walgreens, as a self-distributor, had information about its customers available to it at times. As Walgreens admits, Walgreens's distribution "customers" are the "individual Walgreens

[243] WAGFLDEA00000459.

[244] WAGMDL00289068, at 289153-154.

[245] WAGMDL00037521.

[246] *See* Walgreens 2013 MOA (WAGMDL00490963-978; WAGMDL00387975-982; WAGMDL00387653-974) at WAGMDL00387727, WAGMDL00387760, WAGMDL00387762, WAGMDL00387833, WAGMDL00387866, WAGMDL00387868, WAGMDL00387876, and WAGMDL00387941 (detailing suspicious Florida dispensing to Ohio customers), and at WAGMDL00387753 (describing evidence that "many individuals from Ohio … have travelled by carloads to … Florida to obtain prescriptions for oxycodone….").

pharmac[ies]" and Walgreens had the ability to conduct "data mining… across retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive…." [247]

1) Walgreens's Outside Distributors Flagged Walgreens Stores for SOM Violations and Relied on Walgreens for Due Diligence

In addition to self-distributing, Walgreens knew its pharmacies also received shipments of opioids from outside distributors, including Cardinal, Anda, and AmerisourceBergen.[248] Walgreens not only had access to data regarding the amount of opioids the Walgreens pharmacies were receiving from the outside distributors, but Walgreens knew that the outside distributors relied on Walgreens for some portion of the outside distributors' due diligence.[249] Additionally, Walgreens knew that its outside distributors were flagging its own pharmacies for making suspicious orders for prescription opioids,[250] and yet continued to self-distribute to those pharmacies without reporting any of those pharmacies' orders as suspicious **and without including the additional opioids from third-party vendors in its Suspicious Order Montoring System for most of the time it was self-distributing.**

2) Walgreens's Ordering System for Prescription Opioids

Because Walgreens self-distributed,[251] only distributing controlled substances to its own pharmacies, Walgreens's distribution and pharmacy ordering operations were highly integrated. Walgreens provided stores with suggested orders for controlled substances, with amounts based on the stores' previous orders for that drug. As part of its new SOM program, which was not fully implemented until late 2012/early 2013, Walgreens began to more strictly control the recommended orders and implemented ceilings which more strictly limited stores' ability to exceed the recommended order amounts. As summarized by one of Walgreens's Pharmaceutical Integrity Managers in August 2013:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override …. The purpose for this is to ensure we have performed adequate review before sending in additional inventory.

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[247] WAGMDL00757776.

[248] Bratton Depo (12/16/18), 257:12-258:17; Polster CT1 Depo (1/23/2019), 139:18-140:5.

[249] *See, e.g.* WAGMDL00302958; WAGMDL00246284; WAGMDL00242055; WAGMDL00032660.

[250] *See, e.g.* WAGMDL00302958; WAGMDL00246284; WAGMDL00242055.

[251] During the time in which Walgreens was self-distributing, Walgreens stores also received shipments of controlled substance from outside vendors at various times, including from Cardinal Health, AmerisourceBergen, and Anda. *See* Bratten Depo (12/16/18) 257:12-258:17; Polster CT1 Depo (1/23/2019), 139:18-140:5.

> The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens.[252]

As discussed below, the record confirms that Walgreens's SOM program permitted excess distribution of prescription opioids to Walgreens's pharmacies through at least 2013 without any comprehensive limit or review. This lack of due diligence is in addition to the availability of prescription opioids from other distributors as addressed above.

a) RX Questionable Order Quantity (2006 – Present):

In 2006 Walgreens instituted the Questionable Order Quantity policy, which purported to establish procedures for verifying questionable store order quantities for prescription items.[253] This policy instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. Once all orders were reviewed for accuracy, they were to be processed by the DC. From 2006 to 2010 this policy made no mention of reporting suspicious orders.[254] In 2010 the policy was updated to include language that suspicious store orders and inquiries would be handled through the Corporate Office Internal Audit Department and noted that suspicious orders would be reported to the DEA within 3 days, however the policy gave no specifics as to how or by whom such orders would be reported.[255] There is further no evidence in the record that the Internal Audit department had any involvement in reporting suspicious orders. For example, the Chief Audit Executive at Walgreens could not recall any audit department responsibility concerning specific suspicious orders.[256] This policy was updated again in October 2013 to state that Walgreens Strategic Inventory Management System will stop what would be considered suspicious controlled drug orders from being released for picking.[257]

Walgreens was unable to locate any policies or procedures that Walgreens's DC personnel used to identify suspicious or abnormal orders.[258] Walgreens admits, however, that DCs do not have the ability to detect trends in local markets.[259] Similarly, Walgreens could not locate any training materials related to this procedure[260] and Walgreens DC personnel did not recall receiving any training related to orders deviating from a normal pattern.[261] Further, according to Walgreens's

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[252] WAGMDL00021425.

[253] WAGMDL00757788.

[254] *Id.*

[255] WAGMDL00751821 at 1822.

[256] *See e.g.* Domzalski Depo., 165:6-13.

[257] WAGMDL00749381.

[258] Bratton Depo., 138:4-16; 142:18-143:2; 50:4-51:14.

[259] WAGMDL00659801, at WAGMDL00659817.

[260] Bratton 12/16/18 Depo., 100:21-101:4.

[261] Bish Depo., 72:22-73:23.

DC personnel there were no guidelines for determining what constituted an abnormal or suspicious quantity, but generally anything in the triple digits would be flagged.[262] This meant that a store had to order 100 or more 100 count bottles oxycodone or hydrocodone (10,000 dosages units) before an order would be flagged.[263] Walgreens was also unable to produce any files documenting any due diligence related to this procedure.[264]

The creator of the order quantity query at Walgreens testified the query was not created for the purpose of identifying suspicious controlled substances orders, but was utilized a to identify unusually large orders of any product, regardless of whether the order was for toilet paper, paper towels, Claritin, or OxyContin. Additionally, the excessive order query was never amended or modified for specific use for identifying excessive controlled substances orders.[265] Ultimately, the DC personnel responsible for implementing this policy conceded that it was not intended to detect suspicious orders, but rather was a program designed to detect inventory orders entered in error.[266]

A second aspect of this policy required "pickers", the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.[267] This facet of the RX Questionable Order Quantity policy was not intended to detect suspicious orders as mandated by the security requirement, but as with the general inventory policy, allowed for the identification of orders potentially entered in error.[268]

b) Rigid Formula Reports ("Suspicious Control Drug Order" Reports (1998– 2012)):

Walgreens submitted a monthly report to the DEA field offices containing all orders that were outside the parameters of the formula applicable during that time frame.

Walgreens internally acknowledged, as early as 1998, the requirement to identify controlled substance orders of "unusual size[,]… unusual frequency[,]…[or] [d]eviating from a normal pattern for a store in its category".[269] However, the policy containing this requirement only states that Walgreens is generating and providing "Suspicious Control Drug Orders" reports listing orders that "may" be suspicious "to distribution centers." In 2012, Walgreens updated this policy to assert that "[e]ffective calendar year 2012," Walgreens SOMS system "prevents suspicious

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[262] Bish Depo., 80:16-81:7.

[263] Bish Depo., 80:11-15.

[264] *Id.* at 101:5-13. Walgreens also claims that there were line limits in place that set a maximum upper limit on the quantity per item that could be ordered by a store, however Walgreens was unable to produce any policies, procedures, reports or other written documentation evidencing the line limits or how they were applied to opioid products. Bratton Deposition, 191:24-194:16.

[265] Peterson Depo., 26:9-28:21; 260:15 -262:7.

[266] Diebert Depo., 129:8-130:1 and Bish Depo., 72:3-21, 502:11-503:10.

[267] WAGMDL00749381.

[268] Bish Depo., 110:16-114:5.

[269] WAGFLDEA00001854.

control drugs from being shipped to the stores," and thus Suspicious Control Drug Orders reports would no longer be generated, but again provided no detail on how such a system worked or why such measures were only newly being employed.[270]

i. Customer Grouping Formula (1998-2007)

Walgreens's insufficient formula for reporting suspicious orders to the DEA from at least 1998-2007 is outlined in a 2006 Letter of Admonition from the DEA to Walgreens, and was as follows:The system set its standard of deviation from a normal ordering pattern in groupings of 25 customers, based on the number of non-controlled and controlled substance prescriptions filled by each customer. The system in place determined the amount of daily prescriptions filled by each of its customers of both non-controlled and controlled substance prescriptions. This amount was utilized to place each customer in groupings containing 25 customers. Of these groupings of 25 customers, the firm calculated the average order per item of each controlled substance. The firm then took the average and multiplied that figure by three. This calculated figure was then used as the base to report suspicious orders above such figure. [271]

ii. Formula Based on Chemical Handlers Manual Appendix E-3 (2007 – 2012)

In May 2006 the DEA informed Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient,"[272] and "inadequate" and that Walgreens's suspicious ordering report "formula should be based on (Size, pattern, frequency)."[273] Rather than design and operate a system to identify suspicious orders, Walgreens modified its reporting of suspicious orders to the DEA to use a version of the formula described in Appendix E-3 to the Chemical Handlers Manual ("Appendix E-3").[274] Notably, the Appendix E-3 adopted by Walgreens was virtually identical to the Customer Grouping Formula that the DEA had just told Walgreens was "insufficient" and "inadequate" in that it also utilized a store average multiplied by a factor of 3 to calculate a purchase limit.[275] Despite knowing they were utilizing a formula that they had just been told by the DEA was "insufficient" and "inadequate", Walgreens began reporting to the DEA using this Appendix E-3 formula in March 2007.[276] Walgreens did not perform any due diligence on the suspicious orders identified by these reports prior to shipping

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[270] WAGFLDEA00000028.

[271] WAGMDL00709510. *See also* WAGMDL00757762 at 772-773 (multiplier of 3 was Walgreens's "determination of a suspicious order.").

[272] *Id.*

[273] WAGMDL00709508.

[274] *See* Walgreens's Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Request No. 3.

[275] WAGMDL00400357.

[276] *Id.*

the orders.[277] Walgreens states that a retrospective analysis of the reports calculated using Appendix E-3 was performed, but the individuals that Walgreens claimed performed this analysis stated they had never seen the reports and did not perform due diligence on them.[278] This system simply reported orders that were greater than three times the store's average order for the last 13 months, and only when there were orders in excess of this formula for two or more consecutive months.[279]

Walgreens claims that in 2006 "the Detroit DEA Field Office admonished Walgreens for not basing its reporting of potentially suspicious orders on the "voluntary formula" found in Appendix E-3."[280] However, the documents Walgreens cites for this proposition do not evidence any such admonition and Walgreens has not produced any evidence that it was instructed to base its reporting of suspicious orders on the formula found in Appendix E-3 to report suspicious orders or that it was "admonished" for not doing so. [281] I have not seen any document which supports this contention. Walgreens did produce evidence that in 2007 the DEA informed Walgreens that it did not want reports identifying all potentially suspicious transactions, but rather, only those transactions that Walgreens could not classify as not suspicious after review.[282] A memorandum written by Walgreens employee Justin Joseph outlining the actions taken during the DEA's inspection of Walgreens's Perrysburg DC in 2006 reports that the DEA said that Walgreen's suspicious ordering report "formula" should "be based on (size, pattern and frequency).[283] In fact, documents show that Walgreens was repeatedly told to stop sending the Appendix E-3 type of report.[284]

Further, Walgreens had guidance from the DEA that this type of "excessive report" without any due diligence performed on order did not satisfy the requirements of *21 C.F.R. § 1301.74(b).* Documents produced in this litigation evidence that three of Walgreens's senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas on September 11-12, 2007.[285] Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder

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[277] Bratton Depo., 158:22-159:24. *See also* E. Bratton Errata.

[278] Bratton Depo., 160:1-23; B. Martin Depo., 163:4-168:11.

[279] WAGMDL00400357.

[280] *See* Walgreens Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Response to Request No. 3.

[281] *See* Walgreens Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Response to Request No. 3.

[282] WAGMDL00387635.

[283] WAGMDL00709508.

[284] WAGMDL00660331; WAGMDL00387641.

[285] CAH_MDL_PRIORPROD_DEA07_01185382 at CAH_MDL_PRIORPROD_DEA07_01185404-5.

that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." [286] Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."[287]

Walgreens's internal audit reports demonstrate that Walgreens admitted, as early as February 2008, that its post-2006 SOM system did not comply with CSA requirements.

In a February 2, 2008 internal audit of Walgreens's Woodland controlled substance DC, Walgreens internally admitted that its practices were "non-complian[t]" with "DEA Regulations" including 1301.74 because there is no monitoring process in place to stop a suspicious order to assess if the order is suspicious or not" and because it was "submitting the Monthly Suspicious Control Drug Orders Report to the DEA with numerous instances of filled suspicious controlled substance orders."[288]

In a July 2008 internal audit of Walgreens's Mount Vernon controlled substance DC, Walgreens admitted that it was "filling orders that have been deemed suspicious without performing any research to ascertain the legitimacy of the order, which could lead to the fulfillment of an illicit order."[289] Walgreens further admitted that the "there is no monitoring process in place to prevent the fulfillment of an order if it has been deemed suspicious" and noted that the post-shipment reports of "suspicious controlled drug orders" that Walgreens provided to its DCs and to the DEA is "voluminous which makes it difficult… to use and decipher…"[290]

In a December 2008 internal audit Walgreens's Perrysburg controlled substance DC, Walgreens again admitted "there is no monitoring process in place to stop a suspicious order to assess if the order is suspicious or not," that "Walgreens is submitting the Monthly Suspicious Control Drug Orders Report (SCDOR) to the DEA with numerous instances of filled suspicious controlled substance orders," and that "Walgreens is filling orders that have been deemed suspicious without performing any research to ascertain the legitimacy of the order, which could lead to non-compliance with DEA Regulation Section 1301.74."[291] Walgreens's audit department noted that some of the "issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions," including "issues previously cited in the DEA's May 2006 inspection report that are still open." Among these "DC-wide" issues "requiring the greatest level of improvement" were "suspicious controlled drug order processing and reporting," "controlled drug reporting," and "lack of formalized CII controlled substance policies and procedures."[292]

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[286] CAH_MDL_PRIORPROD_DEA_12_00011059; HDS_MDL_00002032 at 2040.

[287] Acquired_Actavis_00441354 at 441355.

[288] WAGMDLPER00000350.

[289] WAGMDLPER00000353.

[290] WAGMDLPER00000353.

[291] WAGMDLPER00000313.

[292] WAGMDLPER00000001; WAGMDLPER00000020.

Incredibly, one of Walgreens solutions to its failures of its SOM and SOR process to comply with the CSA was to "revisit the report parameters to reduce the report size to a manageable level."[293]

In a 2010 internal audit of Walgreens's Jupiter controlled substance DC, Walgreens admitted that it still "may not be verifying the legitimacy of 'suspicious' orders which could lead to the fulfillment of an illicit order" and that "no monitoring process [is] in place to prevent the fulfillment of an order if it has been deemed suspicious."[294] While the auditor acknowledged "a new suspicious order monitoring process" was "created" and "piloted," they did not know w the "current status of the program."[295]

Perrysburg DC Manager Steve Kneller testified that Walgreens did not recall communicating to DEA during the course of the DEA's post-2008 Perryrburg DC inspections that Walgreens internally determined that Walgreens's SOM system contained no monitoring process, that the SOM system did not stop suspicious orders from being shipped, that Walgreens could be filling illicit orders, and that the orders Walgreens was reported to the DEA as suspicious had already been shipped.[296] Instead, Mr. Kneller told DEA that he was unaware what measures corporate took to investigate suspicious orders.[297]

DEA never approved Walgreens's SOM system, or any use of the Appendix E-3 formula, during the course of DEA's cyclic or scheduled investigations of Walgreens's distribution centers. As DEA 30b6 witness Clare Brennan testified, while DEA investigators are trained to ensure a SOM system is in place, they are also trained not to approve any SOM system.[298]

c) Bancroft Algorithm (2008 to 2012):

i. Phase I (August 2009 – September 2010)

As early as 2005 and 2006, Walgreens acknowledged that its SOM policies were inadequate and did not meet industry and legal standards, however, Walgreens did not institute a SOM program at that time.[299] In March 2008, in response to three of Cardinal Health's DCs being

[293] WAGMDLPER00000020; WAGMDLPER00000313.

[294] WAGMDLPER00000379.

[295] WAGMDLPER00000379.

[296] Kneller Depo., 413:6-421:2.

[297] Kneller Depo., 411:5-412:18.

[298] Brennan Depo., 33:7-17, 84:10-85:24, 137:13-22, 159:8-160:19, 181:16-182:20, and 240:19-241:1.

[299] WAGMDL00757193 ("internal controls that ensure compliance with DEA regulations … pertain[ing] to all company DCs … should be addressed to void potential DEA sanctions", noting that these issues had been pending and "un-remediated" since audits in 2005 and 2006, and included "suspicious controlled drug order processing and reporting" and "lack of formalized CII controlled substance policies and procedures."); *See also* WAGMDL00709508 (""suspicious ordering report is inadequate"); WAGMDL00709510 ("formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient").

shut down by the DEA for suspicious drug ordering violations, Walgreens formed a five department "team" to finally "begin creating" a SOM program,[300] and, in June 2008, developed a new SOMS algorithm to begin to address the inadequacies of Walgreens's SOM policies.[301] Despite years of knowledge that its SOM was insufficient, and despite developing a sophisticated algorithm in 2008, Walgreens did not practically implement its SOM program until 2009, when it began to pilot the algorithm with respect to orders from seven (7) Walgreens stores.[302] The algorithm Walgreens developed in 2008 and began to test in August 2009 flagged the regular periodic orders for controlled substances orders that these seven Walgreens stores placed to Walgreens Distribution Centers for "tolerance" (size of the order) and "frequency" (how often the period orders were placed).

During the substantial majority of Phase I, the SOMS program was only implemented as a "pilot" or "proof of concept". [303] While the Phase I SOMS flagged some orders from these seven stores as suspicious, during Phase I Walgreens did not halt orders that violated the algorithm or take any other comprehensive steps to prevent the flagged orders from being shipped or filled. The SOMS order flagging pilot was not implemented chainwide until September 2010.[304]

The algorithm also was only applied on an extremely limited basis, for example, reviewing only the controlled substances a store ordered from a Walgreens Distribution Center, but ignoring orders that same store was placing for those same controlled substances from an outside vendor.[305]

Rather than report the orders flagged by its SOMS algorithm, during Phase I Walgreens continued to use the formula found in the Chemical Handler's Manual Appendix E-3 to report orders as suspicious to the DEA.[306] Walgreens knew the SOMS algorithm and the E-3 formula did not flag the same orders.[307] Despite this, Walgreens did not report the orders flagged by the Bancroft Algorithm.

ii. Phase II (September 2010 – June 2012)

In September 2010, two years after developing its SOMS algorithm, Walgreens first began to take steps to prevent certain suspicious orders from being filled. In Phase II of Walgreens's SOMS program, Walgreens flagged orders according to its SOMS algorithm on a nationwide basis,

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[300] WAGMDL00659801 at 818; WAGMDL00709395.

[301] WAGMDL00624527.

[302] WAGMDL00667936, at 938 and 940; *see also* WAGMDL00658227.

[303] Bratton Depo., 207:1-210:7; WAGMDL00325170.

[304] Bratton Depo., 208:10-209:24.

[305] Bratton Depo., 225:21-226:7; WAGMDL00325170.

[306] Bratton Depo., 155:17-22.

[307] WAGMDL00660331.

and also began to automatically reduce quantities of certain flagged orders before those orders were filled and shipped by Walgreens distribution centers.[308]

In April 2012, Walgreens created a policy describing its new SOMS program in which it asserted that the SOMS program now would "identify and modify potentially suspicious orders of controlled substances … prior to the order being sent to the warehouse for fulfillment."[309] This is particularly problematic because cutting orders simply circumvents the identification and reporting of suspicious orders. In addition to the fact that cutting orders without reporting the same to the DEA as suspicious fails to comply with Walgreens obligations under the Controlled Substance Act, Phase II as implemented also had significant gaps or loopholes which caused Walgreens to continue to provide its stores with suspicious quantities of controlled substances, including the following:

- Outside Vendor Orders: The SOMS program still only analyzed orders that Walgreens's stores placed to Walgreens's DCs in a vacuum and did not analyze the store orders in the context of orders which the stores were also placing, at the same time, to outside distributors like Cardinal Health, even though Walgreens has possession of and access to that information.[310] Accordingly, if a Walgreens store had already received from an outside vendor orders amounting to what Walgreens had determined to be the store's full quota for a controlled substance, the Walgreens store would still be permitted to order that same full quota from the Walgreens Distribution Center. Rendering the "cutting" of orders meaningless, Walgreens knew that where it reduced a Walgreens DC order, that its store often would place the remainder of the order with an outside vendor.[311] And yet, Walgreens ignored the outside vendor orders and did not report to the DEA when stores would overtly circumvent the "cutting" of orders.

- Interstoring – In addition to obtaining controlled substances from Walgreens Distribution Centers and Outside Distributors, Walgreens stores also obtained controlled substances from other Walgreens stores through the process of "interstoring."[312] Walgreens did not consider these interstore transfers as part of its

[308] WAGMDL00667936, at 940.

[309] WAGMDL00757762, at 773. *See also* WAGMDL00757759, at 761.

[310] Bratton Depo., 258:8-17; T. Polster Depo., 144:18-145:15; WAGMDL00245768 at 00245769.

[311] *See, e.g.,* WAGMDL00325129 at 130 (future "enhancements" to SOM system will "identify stores that had order quantity decreased and then placed order to vendor").

[312] WAGMDL00303305 at 306.

SOM analysis.[313] Controlled substance interstoring continued at Walgreens until April 2013.[314]

- Gradual Increase – the SOMS algorithm only considered 13 weeks of sales data and would recalibrate the thresholds if there was an increase in sales. Therefore, a gradual increase in sales did not result in orders getting cut.[315]

- PDQ Orders – In addition to their regular periodic order for controlled substances from the Walgreens Distribution Centers, Walgreens stores were permitted to place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days. The limits and automatic reductions Walgreens placed on stores' orders to Distribution Centers did not apply to PDQ orders, such that "a store could hit their … limit" on a weekly controlled substance order, and then place daily PDQ orders for that drug, "and far exceed" the monthly cumulative order limits put in place by Walgreens SOM program.[316] Walgreens did not remove oxycodone from PDQ ability until October 2012.[317] Other Schedule II controlled substances were not removed from PDQ until Phase V.[318] It is not clear if Walgreens ever removed schedule III controlled substance, such as hydrocodone from PDQ ability.

- 340B – Walgreens admits that orders pursuant to the 340B program were not included in the initial phases of the SOMS program.[319]

- No comparison to Other Stores – Only Comparison to That Store's History – Walgreens admits that, during Phase II, "each pharmacy is looked at individually."[320]

- Store and/or Product Removal – During Phases I and II Walgreens had the ability to remove both entire stores and products from the SOMS review.[321]

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[313] Bratton Depo., 258:18-260:5; *See also*WAGMDL00303305 at 306 (in early 2013, Walgreens indicated that it was considering including multiple interstore requests within three weeks as a suspicious criterion, but there is no evidence Walgreens otherwise include interstore transfers in its SOMS analysis).

[314] WAGMDL00700161.

[315] WAGMDL00659801 at 00659818.

[316] WAGMDL00705318.

[317] WAGMDL00705318.

[318] Bratton Depo., 271:20-23.

[319] Polster Depo., 256:9 - 257:4.

[320] WAGMDL00757762 at 773.

[321] Bratton Depo., 260:6 -261:4.

- Call DC for Manual Workaround: even when Walgreens began cutting orders over a certain limit, stores could simply "call the DC" to obtain a "manual work around" the purported limit. As Walgreens admitted, the DCs did not have the ability to evaluate information necessary to determine the propriety of any such overrides.[322]

Rather than report the orders flagged by its SOMS algorithm, during Phase II Walgreens continued to use the formula found in the Chemical Handler's Manual Appendix E-3 to report orders to the DEA.[323]

Orders flagged by the SOMS algorithm and reduced in Phase II were not reported to the DEA as suspicious, even though Walgreens's own documents describe these orders as "suspicious orders."[324]

iii. Phase III and Phase IV (June 2012-November 2012)

In April 2012, the DEA served a Subpoena to one of Walgreens's three Schedule II distribution centers, the Jupiter Distribution Center, requesting, among other things, all controlled substance SOPs, communications about controlled substances, and customer due diligence files for 14 Walgreens stores, and also served a Warrant of Inspection on the Jupiter Distribution Center, authorizing seizure, among other things, all records related to distribution of controlled substances.[325] On September 13, 2012, the DEA issued an Order to Show Cause and Immediate Suspension of Registration to Walgreens on the basis that the Jupiter Distribution Center constituted "an imminent danger to the public health and safety" and ordered that Jupiter controlled substance vault be sealed.[326]

During the latter half of 2012, after the DEA instituted its regulatory investigation and action regarding Walgreens's controlled substance distribution practices, Walgreens engaged in meetings with the DEA about Walgreens's "Controlled Substance Anti-Diversion and Compliance Program" in an effort to "cooperate and avoid litigation," and represented to the DEA that it was making "new changes" to "enhance" its SOMS program.[327] Internally Walgreens claimed that it

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[322] WAGMDL00659801 at 817-818.

[323] Bratton Depo., 155:17-22.

[324] Bratton Depo., 227:1-5; WAGMDL00624503; WAGMDL00119542.

[325] WAGMDL00777158; CAH_MDL2804_01431074.

[326] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387654 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012) ["Jupiter Show Cause Order"]).

[327] WAGMDL00659801 at 802.

enhanced its SOMS program "in an effort to convince DEA that the proposed penalty is excessive…"[328]

While these changes narrowed some of the more significant gaps in the SOMS program, many still remained in Phase III, which ran from June 2012 through August 2012, and in Phase IV, which ran from August 2012 to November 2012.

Phase III of the SOMS program began to incorporate outside vendor orders into the overall SOMS analysis, but only when analyzing order frequency – not in analyzing the tolerance (i.e. overall limits).[329]

The other gaps which existed in Phase II also generally continued in Phases III and IV. For example, where a Walgreens store's order was reduced before being fulfilled by the Walgreens DC, Walgreens still allowed the store to order the rest of the amount from an outside vendor (i.e. Cardinal), but now tracked that information on a report.[330]

Orders flagged by the algorithm and reduced in Phase III and IV were not reported to the DEA as suspicious, even though Walgreens' own documents continue to describe these orders as "suspicious orders."[331]

iv. Phase V (November 2012 forward)

Phase V changed the frequency algorithm to "ceiling limits" which looked at the overall total a Walgreens store was ordering before allowing the Walgreens Distribution Center to fill the order, finally incorporating orders from outside distributors into a more comprehensive analysis.[332]

Phase V eliminated the "frequency" analysis and implemented a "ceiling threshold" in January 2013, examining all orders placed by a store within a giving time period. Walgreens also began cutting a store's order to zero when the store manually manipulated a suggested order or created an order that exceeded the tolerance or ceiling.[333]

Walgreens's own documents admit that it made the ceiling limits visible to the stores in advance via a "ceiling tool" and further admit that the purpose of this "ceiling tool" was to provide stores visibility into the likelihood of an order being flagged – and possibly a means to work around

[328] WAGMDL00659270.

[329] Bratton Depo., 254:14-21; WAGMDL00325170, at 174; Bratton Depo., 226:4-12.

[330] WAGMDL00492378.

[331] Bratton Depo., 227:1-5.; WAGMDL00325170 at 172.

[332] Walgreens Second Supplemental Combined Discovery Responses, at p. 16.

[333] WAGMDL00246016.

it – stating "the ceiling tool was designed to provides stores direction to place orders for controls without an order being flagged."[334]

Walgreens's last CII shipment as a distributor to Lake and/or Trumbull County was March 2013.[335]

6. <u>Due Diligence Conducted</u>:

Due Diligence, as discussed in more detail in other areas within this report, relates to the KYC process and specific investigations related to potential suspicious orders in an effort to determine if said orders may be shipped. Walgreens conducted very limited and irregular due diligence prior to the formation of the Pharmaceutical Integrity Department in late 2012/beginning of 2013. For example, limited pre-2012 emails produced by Walgreens reveal that the "warehouse" (Walgreens DC) would call stores to inquire about large orders, but those orders would be cleared if the store confirmed that they were intentionally placed.[336] Even after the creation of the Pharmaceutical Integrity Department, Walgreens did little due diligence and did not keep complete records of any due diligence performed outside of a relatively small number of emails beginning in 2012[337] and sparse database notations about limited orders in and after 2013.[338] Walgreens failed to produce any due diligence records pre-dating 2011. The limited documents Walgreens listed in its CT3 Interrogatory 2 responses regarding purported opioid due diligence from this time period do not reflect any SOM due diligence, but rather only address whether the requested amount of drug was shipped or whether there was a shipping or inventory error. Walgreens's failure to retain historical records and failure to incorporate historical due diligence information into its SOMs program is problematic because an important aspect of every due diligence review should always be an examination of the historical of the customer who placed the flagged order. Without such information, one cannot fully evaluate trends over time or make fully informed decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels.

Walgreens claims that it engaged in "a variety of practices" for conducting due diligence on potentially suspicious orders over time.[339] One of the practices Walgreens specifically points to is that from "time to time, the distribution centers' function managers also sought input from personnel in Rx Inventory, who, upon request, reviewed sales history, order history, and item movement for individual stores, to determine whether orders were in line with a store's history or

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[334] WAGMDL00095316 at 322.

[335] *See* ARCOS Transactional Data (this excludes Codeine Drug Code 9050).

[336] *See, e.g.,* WAGFLDEA00000459.

[337] *See e.g.* WAGMDL00107532.

[338] *See* WAGMDL00400358 (ohio_cso_override_history_updated_drug_list.xlsx) (containing limited to information from Sept 2013 – Sept 2018); WAGMDL00400360 (ohio_flagged_orders.xlsx) (only shows certain flagged orders from Sept 2016 – Sept 2018).

[339] Walgreens Second Supplemental Responses to Combined discovery, Request No. 7.

were unusual."[340] Walgreens points to two documents and the testimony of two individuals, Rx Inventory manager, Barbara Martin and Perrysburg Distribution Center CII Function Manager, Deborah Bish, to support this claim.

The first document Walgreens cites is an email chain dated January 10, 2011, between the Jupiter DC CII Function Manager, Kristine Atwell, and Rx Inventory manager, Barbara Martin. In the email chain, the Ms. Atwell expresses concern that she has "several stores that are ordering huge quantities of 682971 on a regular basis."[341] The item Ms. Atwell refers to as "682971" is Walgreens Inventory Checker ("WIC") number for 30 mg oxycodone.[342] Ms. Atwell goes on to state, "I feel that the store needs to justify the large order quantity. Three stores that come to mind are #7298, #3836 and #5018."[343] Ms. Martin responds and provides sales history for two of the three stores specifically mentioned, notes that the third store's system was down, and states, "You can contact the store for more information if necessary. These sales are quite high compared to other non-Florida stores." Apparently unsatisfied with Ms. Martin's response, Ms. Atwell replies stating, "I ran a query to see how many bottles we have sent to store #3836 and we have shipped them 3271 bottles between 12/1/10 and 1/10/11. I don't know how they can even house this many bottle to be honest. How do we go about checking the validity of these orders?" Ms. Martin responds identifying the district pharmacy supervisor's cell phone number and telling Ms. Atwell that he "may be able to shed some light on the subject."

The second document cited by Walgreens is a continuation of the email chain which resumed the following day. Ms. Atwell asks for information regarding the store #3836, the store that Ms. Martin could not access the previous day. Ms. Martin responded relaying that the store had average weekly sales of 36,200 dosage units which was equal to 362 bottles per week and noting, "have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)."[344]

Despite having raised these concerns from the DC to a supervisor at corporate headquarters, it appears that this exchange is the full extent of the "due diligence" performed on the "huge quantities" of oxycodone identified by Walgreens's DC personnel and was typical of Walgreens's due diligence process.[345] There is no evidence of any actual due diligence beyond this facially insufficient email exchange. Further, despite the fact that questions had been raised about this store #3836's ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same

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[340] *Id.*

[341] Martin Depo. Ex. 30 (WAGFLDEA00000846).

[342] WAGMDL00436802.

[343] Martin Dep. Ex. 30 (WAGFLDEA00000846).

[344] WAGFLDEA00000852.

[345] Martin Depo., 337:16-338:19; Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658.

pharmacy.[346] This one store, located in Port Richey, Florida, a town of less than 3000 people in a county with a population of only approximately 475,000, went from 344,000 units of oxycodone in 2009 to 1,406,000 units of oxycodone in 2011.[347] Walgreens also cites to the testimony of Ms. Martin as supportive of this type of due diligence, however, in her deposition, Ms. Martin, the Walgreens inventory manager responsible for performing due diligence on this order, stated that she never even attempted to determine the size of the community that was receiving these "huge quantities" of oxycodone.[348] She further testified that she was not near that store, did not have access to the store's prescriptions or patient information, and couldn't take any "direct action."[349] It is not surprising that approximately 18 months after this email exchange, store #3836 was one of the stores for which Walgreens agreed to surrender DEA registration.[350] Ms. Martin's response confirms that Walgreens was not performing the required and appropriate due diligence.

Walgreens also cites to the testimony of Deborah Bish, the CII function manager at Walgreens's Perrysburg DC. However, Ms. Bish could only recall one instance in the entire time she was a the CII Function Manager, from October 2002 to present, that she contacted Ms. Martin regarding a questionable order.[351] Further, Ms. Bish testified that the one time she elevated an order to Ms. Martin, Ms. Martin cleared the order to be delivered.[352]

This type of inadequate due diligence evidences Walgreens's systemic failure to protect against diversion. Walgreens, when notified by its own employees of the presence of indicators of the pending threat of diversion, took no action to prevent diversion. This failure is a total disregard of the maintenance of effective controls against diversion.

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by Walgreens has generally been substandard at best. Walgreens practice of attempting to catch and correct ordering errors at the distribution center level is and inventory management program and does not satisfy Walgreens due diligence obligations. As noted below, Walgreens admits that they performed no pre-shipment or post-shipment due diligence on any orders that were flagged by their Rigid Formula Reports. Additionally, even when Walgreens began to cut orders that exceeded their "tolerance," "frequency," or "ceilings," their policies did not call for appropriate due diligence to be performed

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[346] Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658.

[347] Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387656-58; Martin Depo., 343:22-351:17.

[348] Martin Depo., 349:7-350:12.

[349] Martin Depo., 337:16-338:19.

[350] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658.

[351] Bish Depo., 28:4-10; 89:15 to 91-10 and Exhibit 3.

[352] Bish Depo., 89:15-91-10.

on such orders and did not specify what constituted appropriate due diligence. While I am aware that Walgreens claims it conducted due diligence via email, phone calls, or other undocumented means, my review of the materials as referenced herein belie those claims, indicate that such actions rarely occurred, and that even when they did occur, they fell short of what is required.

7. Reporting Requirement

Walgreens failed to timely report any suspicious orders for the CT3 jurisdictions. The Rigid Formula Reports, used from approximately 1985[353] through 2012, were an after-the-fact reporting which is insufficient. Walgreens has not been able to produce suspicious orders that were reported to the DEA after 2012 and before Walgreens ceased distribution in 2014.[354]

As discussed above, in its written discovery responses,[355] other than the Rigid Formula Reports, Walgreens only identified two "suspicious orders of opioids" by Ohio Walgreens stores from 2006-2014 that Walgreens reported to the DEA: a 12/09/2013 order for Hydrocodone by a Chillocothe, Ohio store,[356] and a 5/8/2014 order for suboxone by a Columbus,columbus Ohio store.[357] In its responses, Walgreens also disclosed a spreadsheet listing 28 opioid orders for Ohio stores between May 2013 and January 2014, however, it is unclear from the face of the document whether these 28 Ohio orders were actually sent to the DEA.[358] Walgreens testified no due diligence was conducted on the orders listed in the Rigid Formula Reports.[359]

Using any of the methodologies described in the Expert Report of Craig McCann, it is apparent Walgreens failed to report thousands of suspicious orders arising out Lake County and Trumbull County.[360]

8. Shipping Requirement

a. Period 1 (1996-2009)

Even if Walgreens had properly identified suspicious orders, which it did not, its corporate policy from 1996 to 2010 was to ship anyway. This is a blatant violation of the No-Shipping requirement. As stated earlier, Walgreens did not perform any due diligence on the suspicious orders identified by the Chemical Handler's Manual Appendix E-3 formula prior to shipping,

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[353] WAGMDL00660331.

[354] Walgreens Response to CT3 Interrogatory 3 and documents cited therein.

[355] Walgreens CT3 Second Supplemental Responses to Combined Discovery Requests at Request 3.

[356] SORS-000234.

[357] SORS-000234.

[358] WAGMDL00852039.

[359] Bratton Errata.

[360] Section IV, "Identifying Suspicious Orders Distributed in CT3."

despite the fact that even the Chemical Handler's Manual (on which Walgreens claims it was relying) requires due diligence prior to shipment. [361]

Though Walgreens initially claimed that a retrospective review of a sample of these orders was reviewed for appropriateness[362], the Walgreens employee identified as performing this review stated that she had never reviewed these reports and did not perform due diligence on these orders.[363] Walgreens subsequently admitted no due diligence had been conducted on any of the orders identified as "suspicious" on the Suspicious Control Drug Report prior to shipment of these orders.[364] In August 2010 Dan Coughlin, Walgreens Divisional Vice President Supply Chain, sent an email to many of those involved in the development of the Bancroft algorithm asking who had been reviewing the reports generated by the Appendix E-3 formula for the past 25 years and whether any was presently reviewing "what would be considered suspicious quantities that are physically ordered and are releasing to stores?"[365] Despite the fact that this email was sent to ten people, most of whom were identified by Walgreens as having been involved in developing Walgreens's order monitoring system or in monitoring or evaluating orders, Walgreens did not produce any evidence indicating that anyone had ever reviewed these suspicious orders prior to shipment.[366]

Walgreens claims that from 2006 through the time that Walgreens stopped distributing controlled substances, Walgreens's DC personnel called stores with orders greater than a set threshold quantity and inquired whether the quantity was actually needed, before shipping the order.[367] As noted previously, this process (Rx Questionable Order Quantity) was not a due diligence practice instituted to investigate suspicious orders, but in fact was an inventory management practice intended to identify ordering errors.[368] Walgreens was unable to produce any policies reflecting what the procedures were for determining a "suspicious order" at the DC level or what the set thresholds were for any controlled substances,[369]and the Perrysburg DC personnel in charge of Schedule II and III controlled substances were never trained on suspicious orders or identifying the same.[370] In May 2012, the Perrysburg DC personnel questioned whether the quantities they typically "let go" were correct and asked for "real, updated guidance on drugs that

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[361] *See* Bratton Depo., 158:22-159:24; Bratton Errata. *See also* WAGMDL00395965 at 988.

[362] *Id.*; Bratton Depo., 160:1-23.

[363] Martin Depo., 163:4-168:11; Bratton Errata.

[364] Bratton Errata.

[365] WAGMDL00660331.

[366] Walgreens CT1 Second Amended Obj. and Resp. to First Set of Interrogatories, Interrogatory 5.

[367] Walgreens CT1 Second Supplemental Responses to Combined Discovery, Request No. 7.

[368] Diebert Depo., 129:8-130:1 and Bish Depo., 72:3-21 and 502:11-503:10.

[369] Bratton Depo., 138:4-16; 142:18-43:2; 50:4-51:14.

[370] Diebert Depo., 61:2-23 and Bish Depo., 64:19-23, 66:7-22, and 401:14-17.

are going to be an issue if the DEA audits…"[371] DC personnel further indicated that because large orders of opioids such as oxycodone, methadone, and fentanyl were so common that it was impractical to call and check large orders, and, that when the DC did call and check orders, they typically learned that the orders were "intentional" and thus appropriate to approve under Walgreens's operative DC level SOMS program.[372] This lack of written procedures and guidelines used to determine what could constitute "suspicious orders", as well as the lack of any enforcement of the policy on calling pharmacies led to a total failure of any meaningful due diligence at the DC level throughout the time period that Walgreens was distributing controlled substances.

As discussed above, Walgreens internal audits admit that, during time this, there was "no monitoring process in place to stop a suspicious order to assess if the order is suspicious or not" and that Walgreens was "filling orders that have been deemed suspicious without performing any research to ascertain the legitimacy of the order"[373]

b. **Period 2 (2009-2012)**

Walgreens admits that, since at least 2009, the DEA had instructed Walgreens to "stop what was considered suspicious drug shipments to any of our stores."[374] During the 2009 to 2012 period, Walgreens claims personnel in Rx Inventory and Loss Prevention conducted additional due diligence on potentially suspicious orders, by reviewing reports of orders hitting on the SOMS threshold limits for tolerance and frequency.[375] This additional "due diligence" consisted of a review of samples of reports of flagged orders generated by the SOMS algorithm **after the orders had already shipped,** in order to validate the algorithm's logic – not to determine whether the order was in fact suspicious.[376] Additionally, this additional "due diligence" was performed by two Walgreens individuals, one of whom dedicated a mere one to ten hours a week to review of the suspicious orders flagged by the SOMS algorithm.[377] As of August 2010, the Walgreens algorithm was generating 389+ pages of suspicious order data per week.[378]

c. Period 3 (2012-2014)

Pharmaceutical Integrity ("RX Integrity") was formed in 2012 as a result of the DEA investigation into Walgreens CSA violations and viewed its role as protecting the DCs and stores

[371] WAGMDL00751871.

[372] WAGMDL00751871.

[373]WAGMDLPER00000001;WAGMDLPER00000020;WAGMDLPER00000313; WAGMDLPER00000350; WAGMDLPER00000353; WAGMDLPER00000379.

[374] WAGMDL00660331.

[375] Walgreens CT1 Second Supplemental Responses to Combined Discovery, Request No. 7.

[376] Martin Depo.,169:5-170:4; 253:4-15.

[377] Martin Depo., 70:10-12; 328:5 to 329:7.

[378] WAGMDL00660331.

from losing their DEA licenses.[379] After referring to orders flagged by Bancroft algorithm as "suspicious orders" since the inception of the algorithm, in late 2012 Walgreens put together a team to "begin the determination between a suspicious order and an order of interest"[380] From this point forward, RX Integrity took the position that the orders flagged by Walgreens's algorithm were not "suspicious" under the controlled substances regulations (despite being described as such in Walgreens own documents), but rather were "orders of interest."[381] Furthermore, as of January 2013 the RX Integrity team only had the ability to investigate orders placed via a Controlled Substance Override ("CSO") Form.[382] The orders flagged via the Walgreens algorithm were a week old and in most cases had already shipped by the time that RX Integrity had the visibility to investigate them.[383]

RX Integrity lacked the necessary resources to perform adequate due diligence on the overwhelming number of orders identified by Walgreens's algorithm for Walgreens 5,000 plus stores.[384] In December 2012 when Walgreens's "updated" SOM program was set to "tracking" for all controlled substances chainwide, it resulted in 14,000 flagged orders that required due diligence reviews.[385] At the time these 14,000 orders were flagged, Walgreens's RX Integrity department consisted of fewer than 5 people, and at its height it only had had eleven members.[386] Walgreens had the ability to control this workload by simply increasing stores' ceiling values, thereby reducing the number of orders that would breach that ceiling.[387]

One of the mechanisms that Walgreens put in place to deal with the number of flagged orders was the CSO system, an "alternative ordering procedure" to be used in response to demand increase.[388] Orders that exceeded the Walgreens algorithm were cut to predetermined limits unless an override was approved. When Walgreens stores were close to hitting their ceiling limits they were directed to complete a CSO Form.[389] The RX Integrity team of eleven was then tasked with reviewing the CSO Forms and making decisions with regard to override approvals. At times, the RX Integrity team received between 1,000 and 3,000 CSO forms per month.[390] When CSO

[379] WAGMDL00101723; WAGMDL00060486.

[380] WAGMDL00574824 at 825.

[381] Polster Depo., 174:3-176:18.

[382] WAGMDL00414048.

[383] WAGMDL00414048; WAGMDL00415348.

[384] Polster Depo., 133:10-13.

[385] WAGMDL00659270.

[386] Polster Depo., 240:3-15.

[387] WAGMDL00370894 at 00414048.

[388] WAGMDL00037074.

[389] WAGMDL00700240; WAGMDL00095316 at 334.

[390] Polster Depo., 343:15-23.

overrides were submitted they were routinely approved. For example, Walgreens documents show that over 95% of CSO overrides were approved by RX Integrity in both 2014 and 2015.[391]

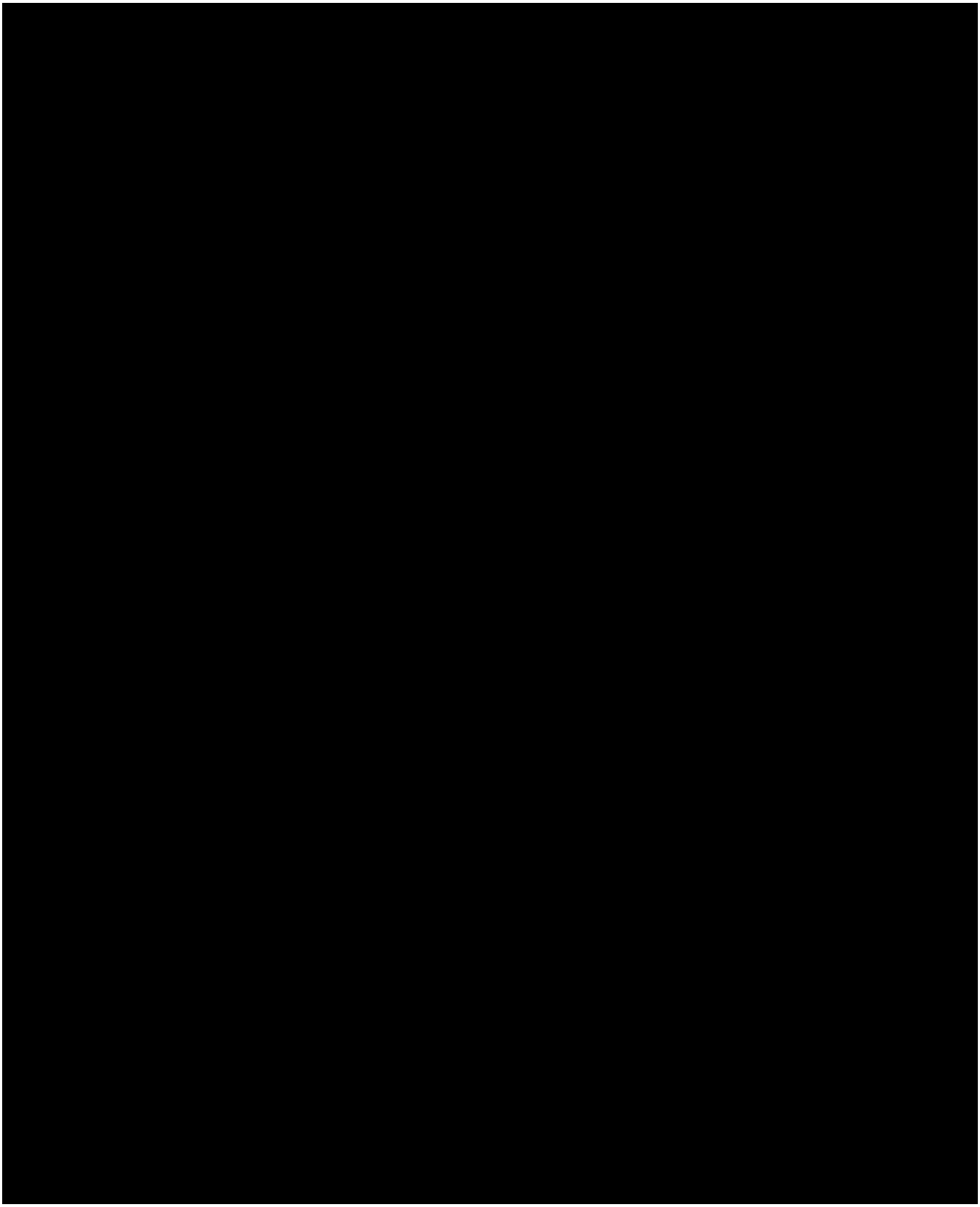
[redacted]

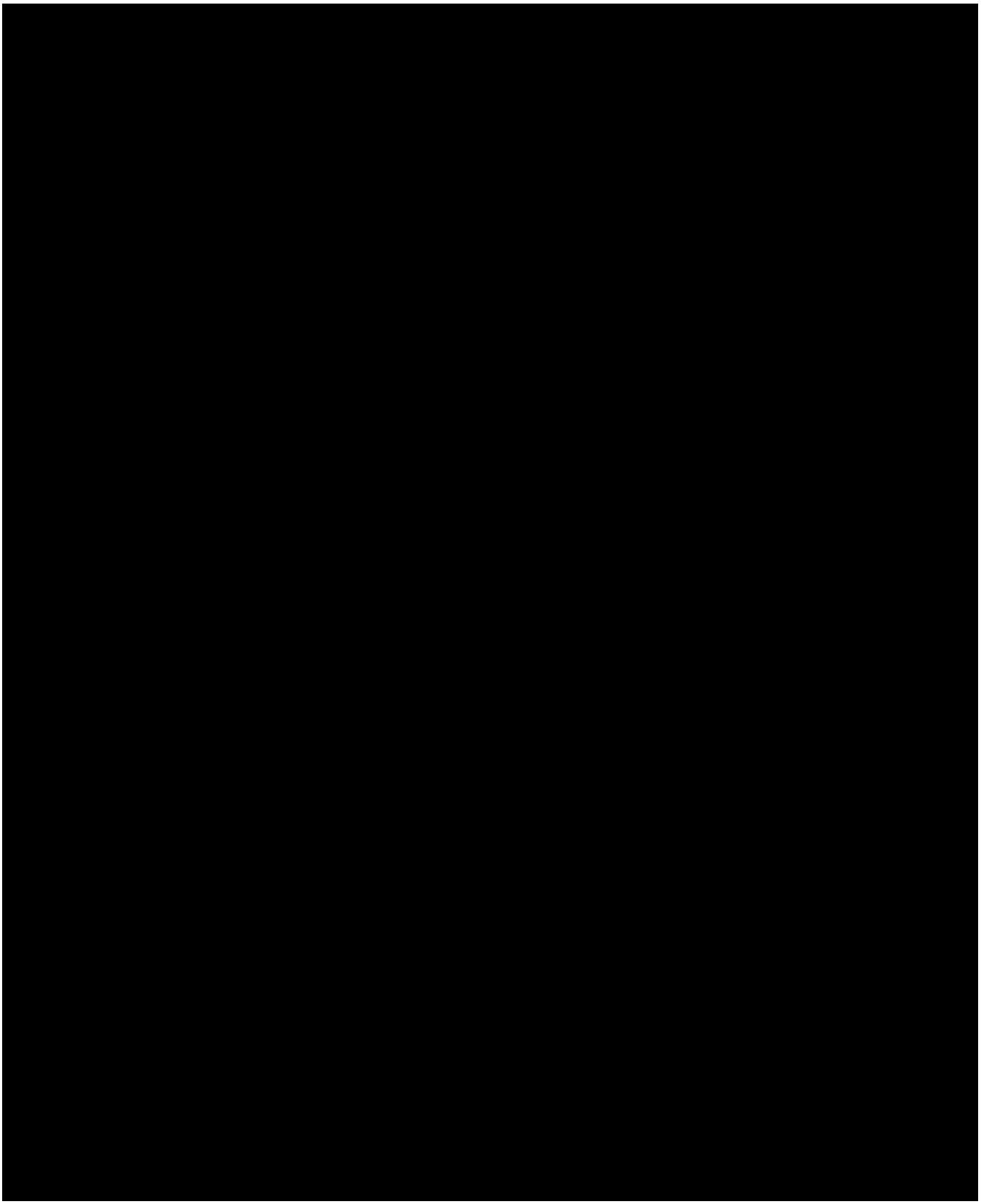
[redacted]

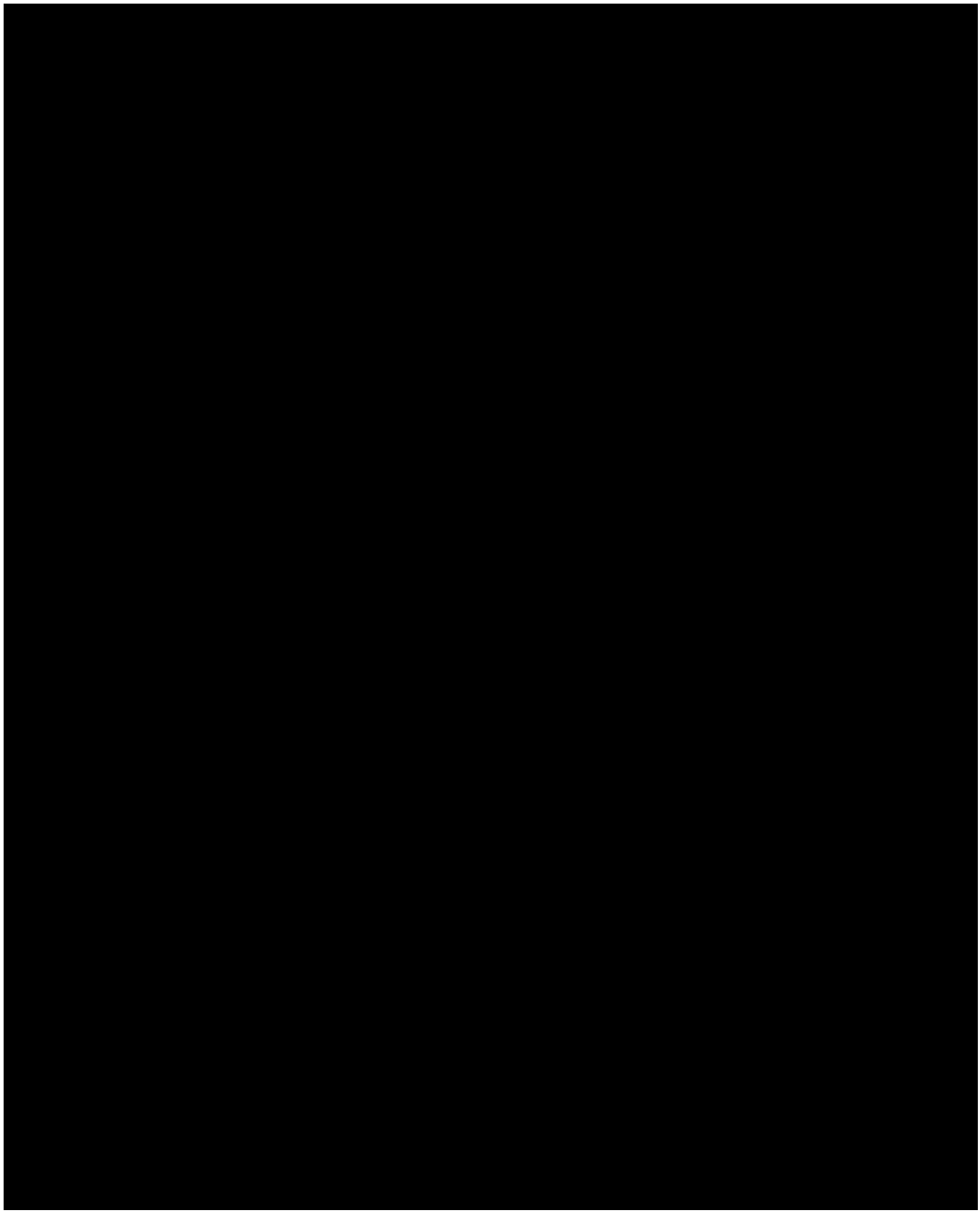
[391] *See* Walgreens Presentation *State of Rx Integrity* (May 10, 2016) WAGMDL00010887 at WAGMDL00010909.

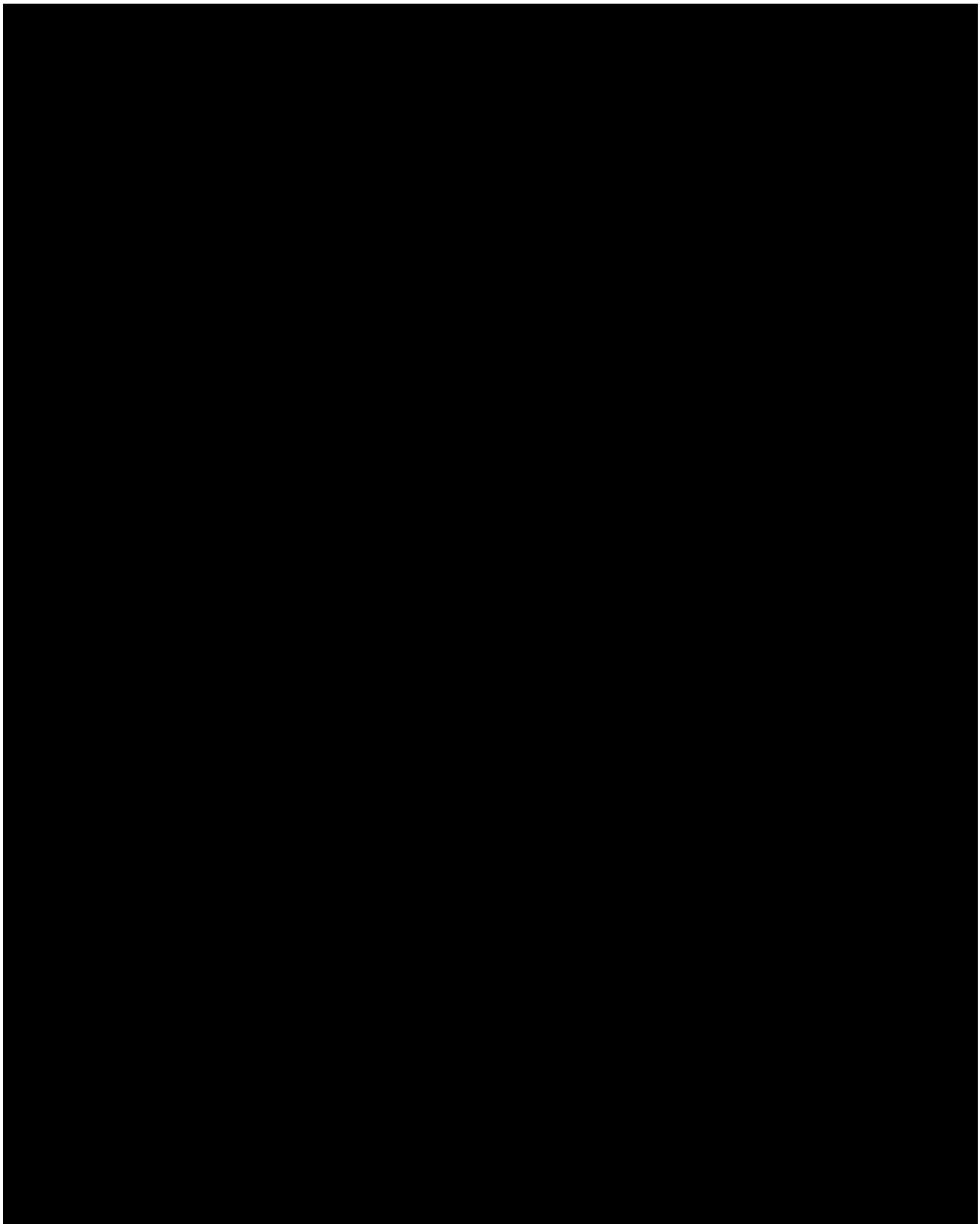
[392] Report of McCann, Appendix 8.

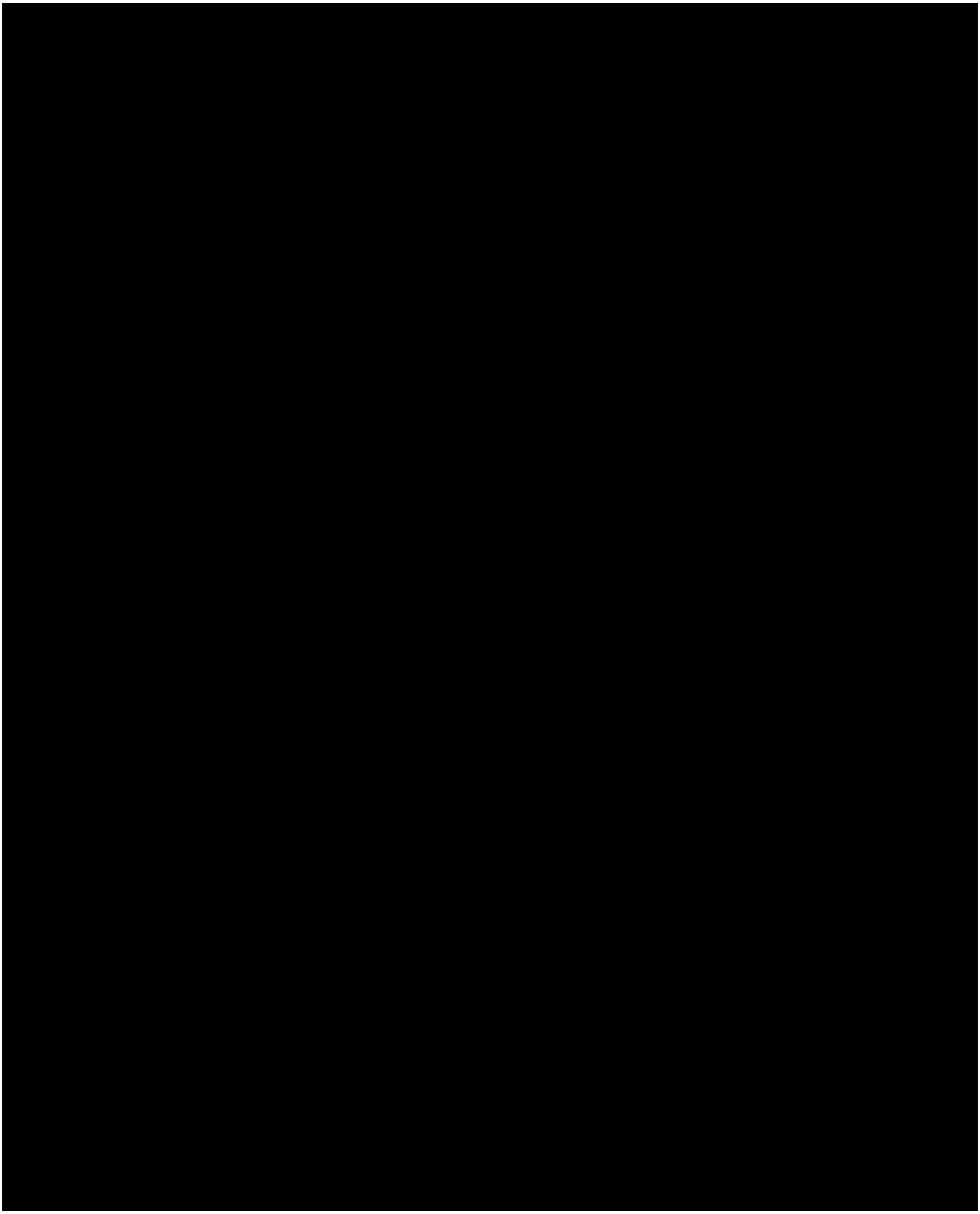
[393] *Id.*

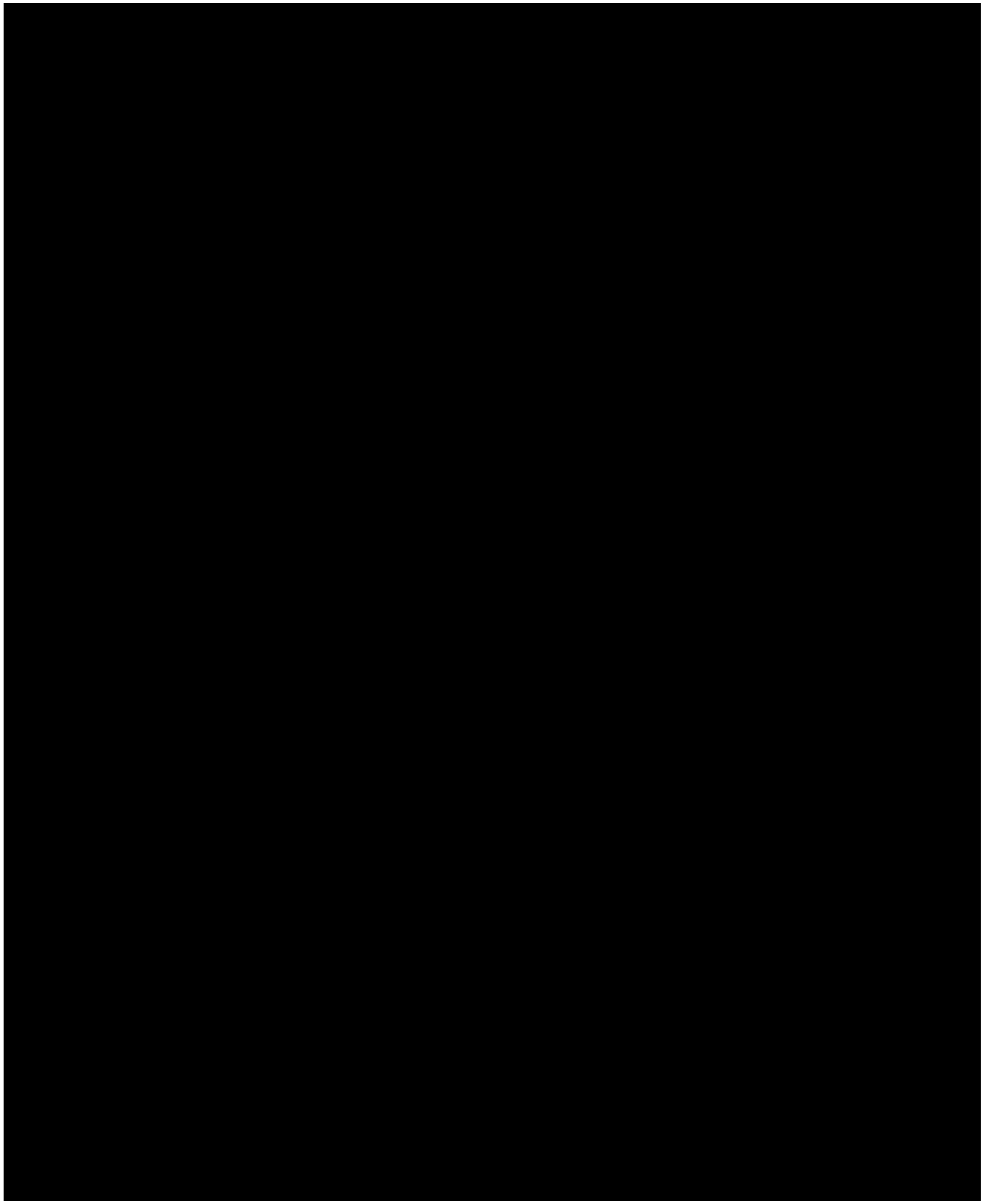


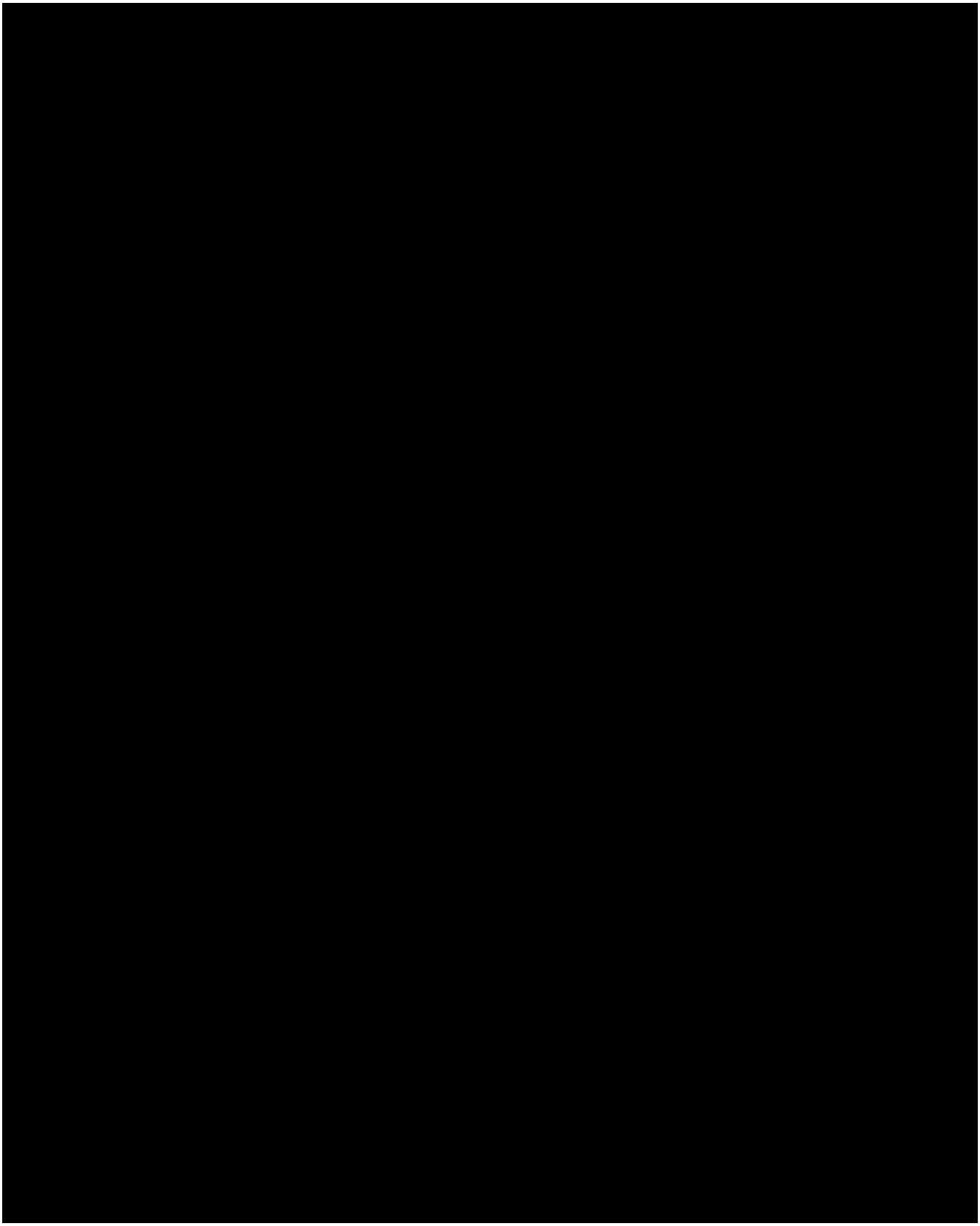


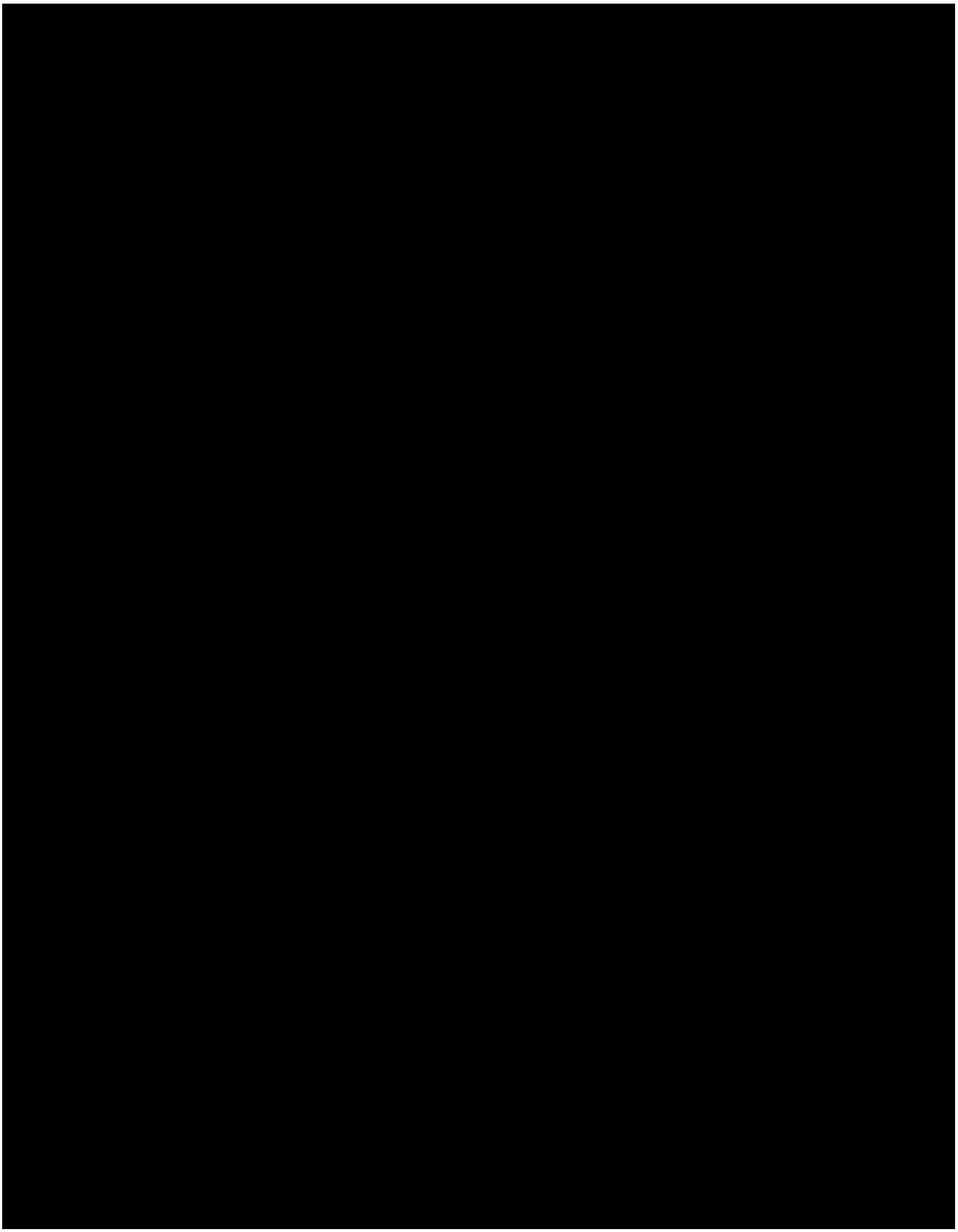


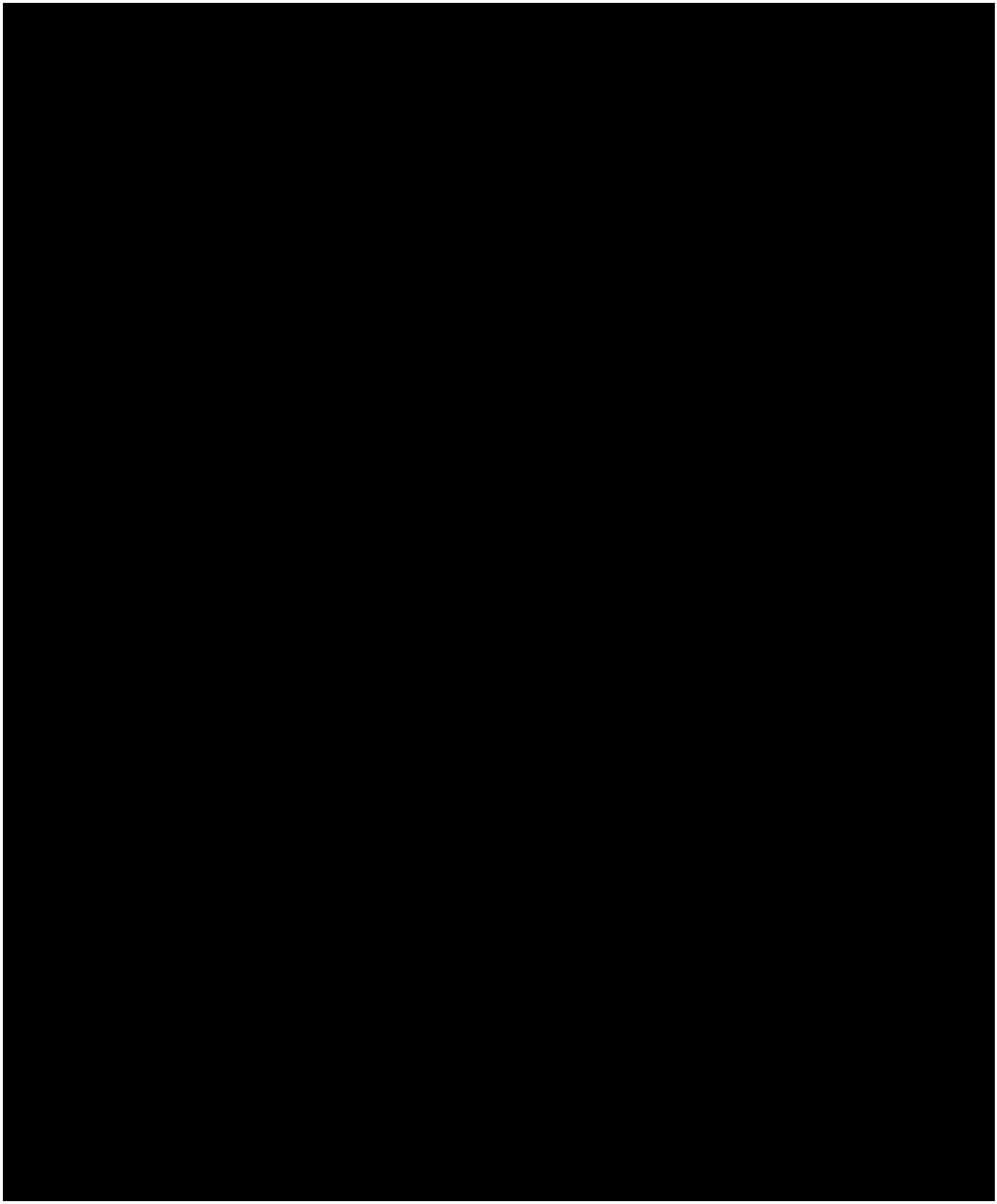


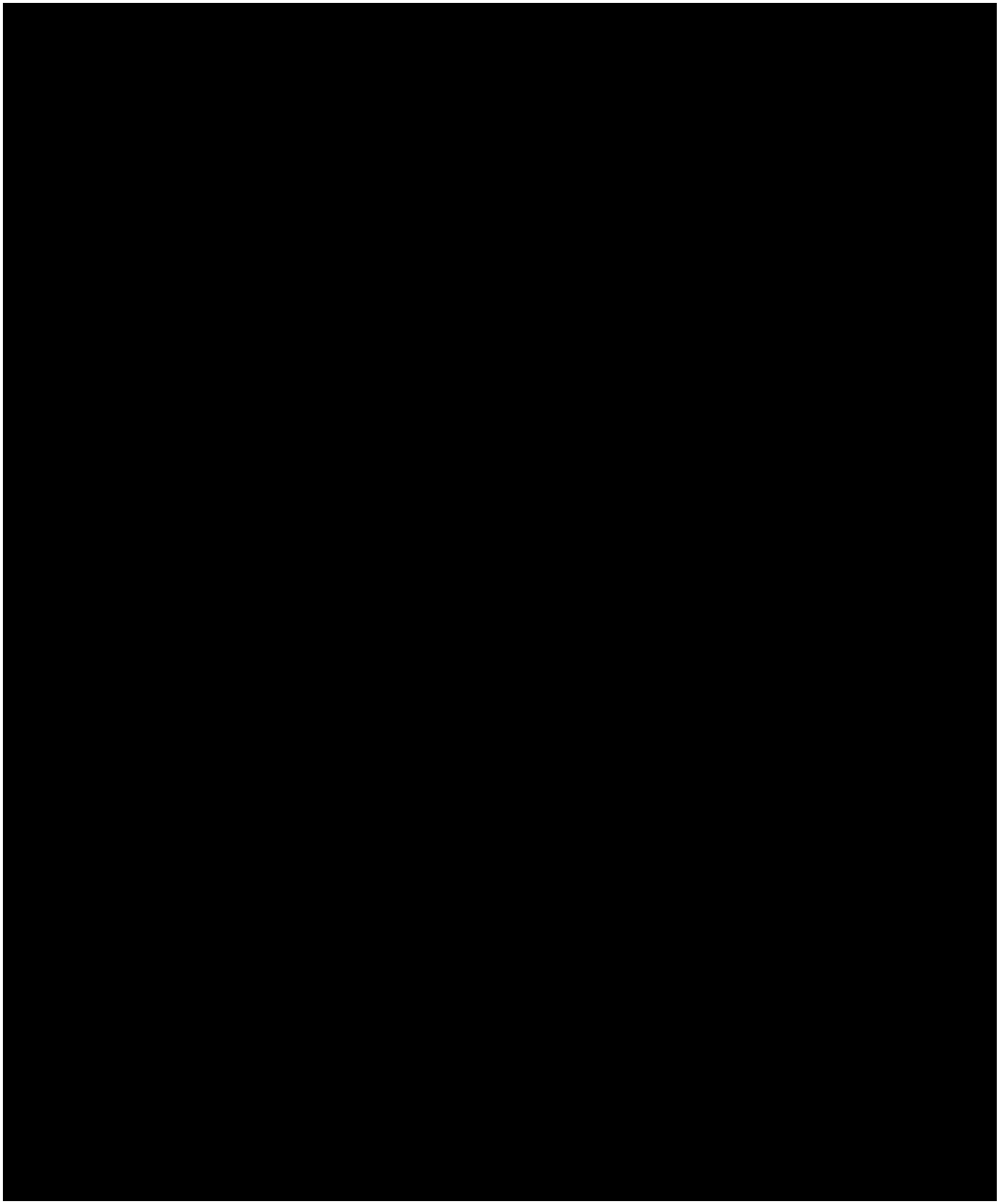


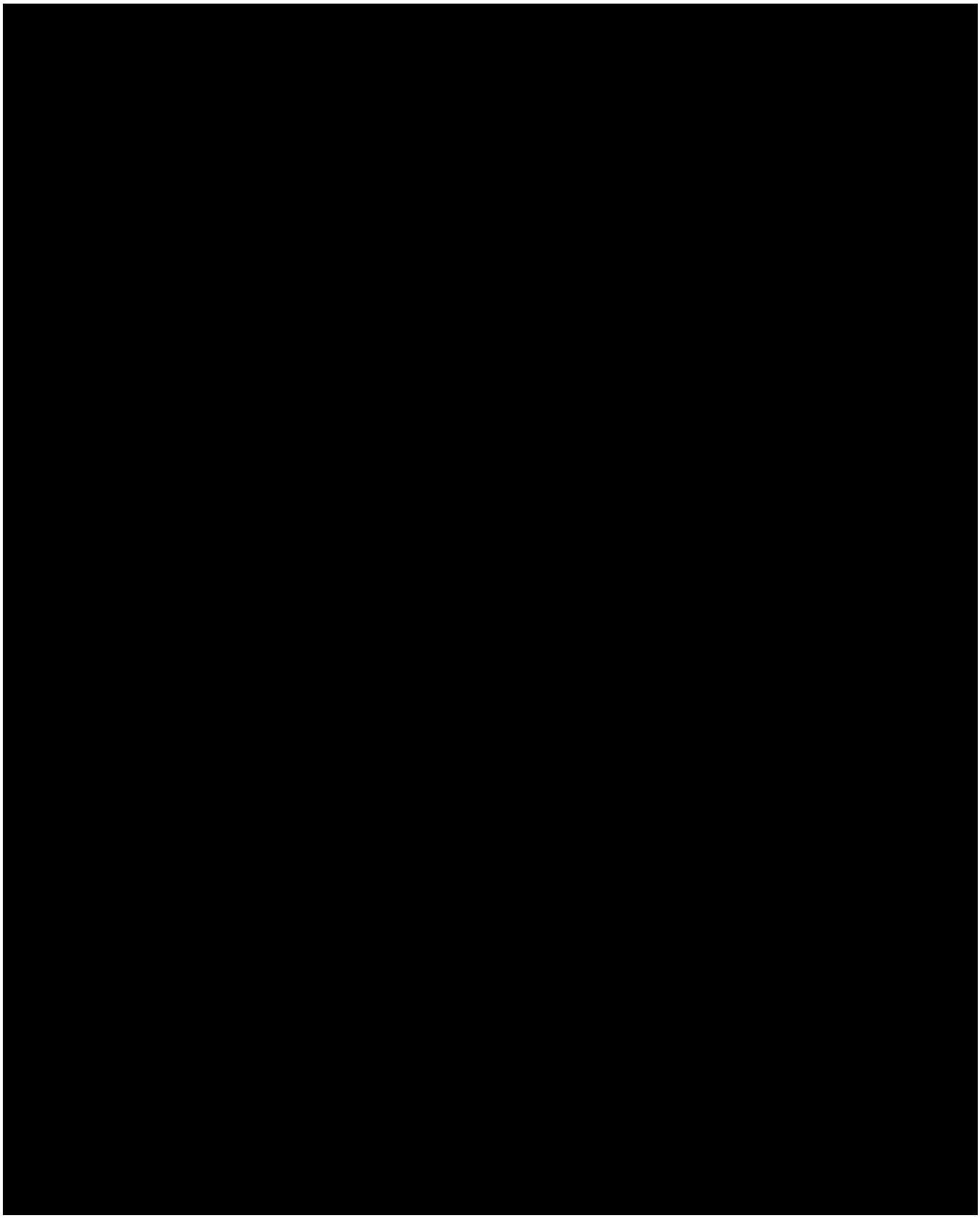


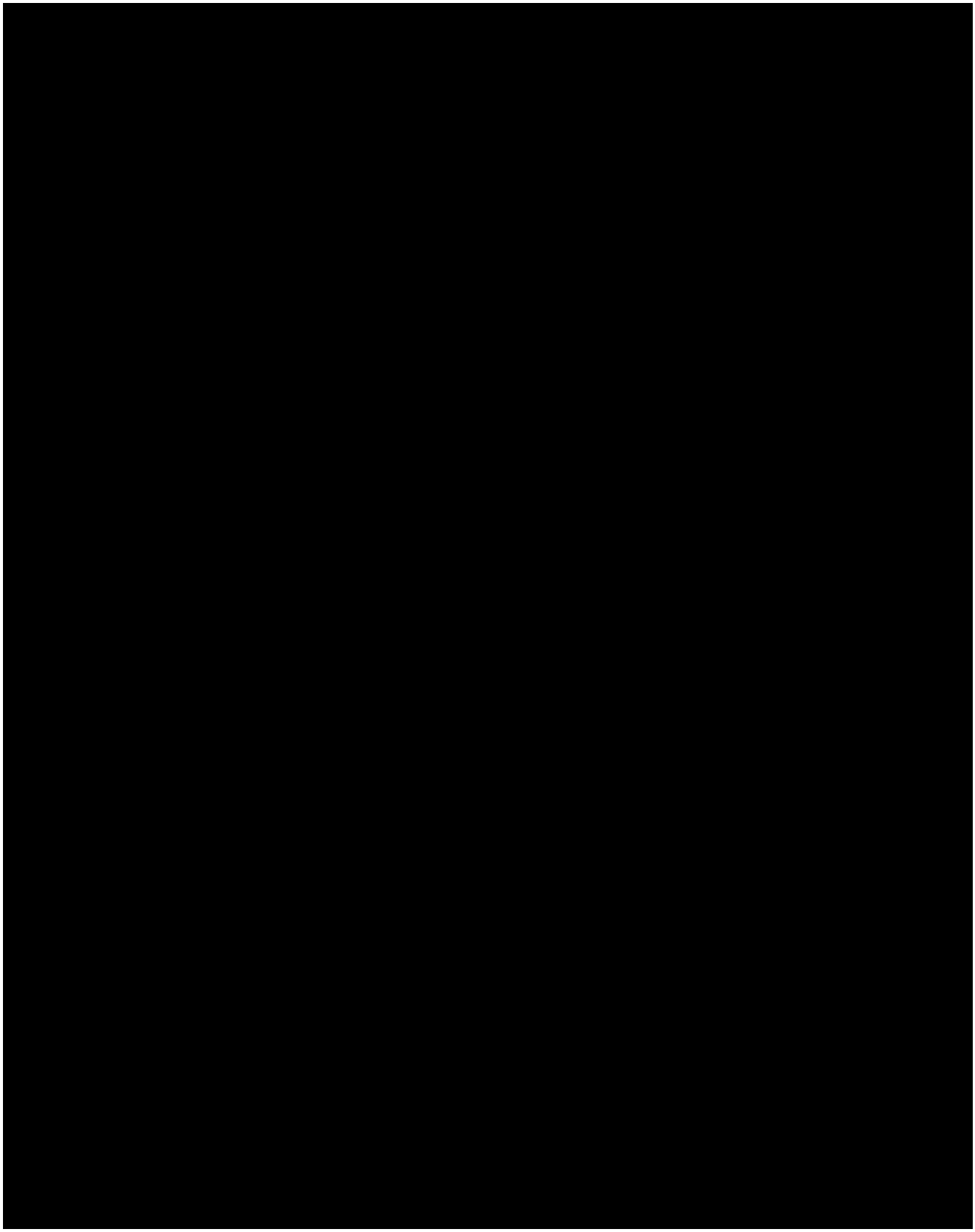


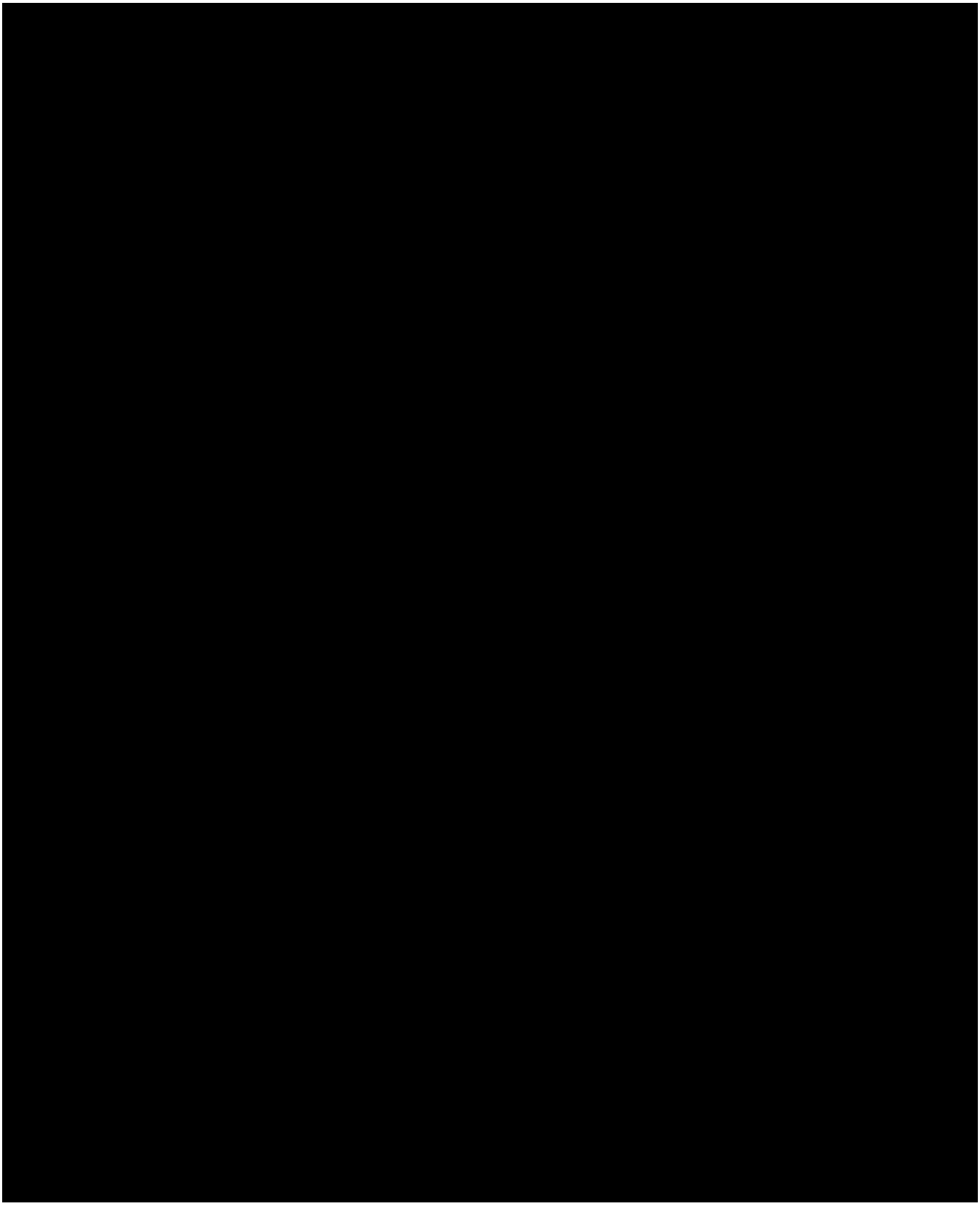


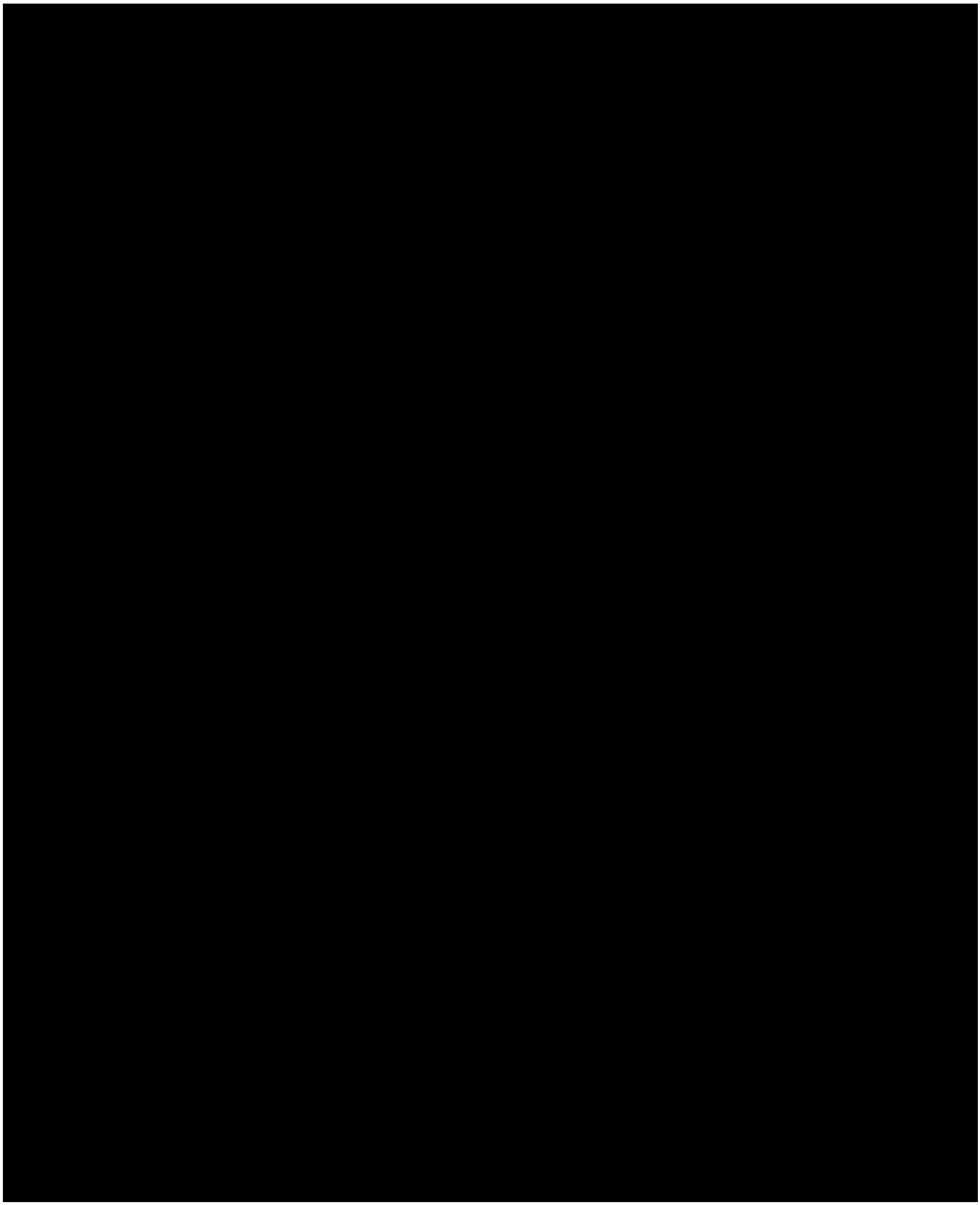


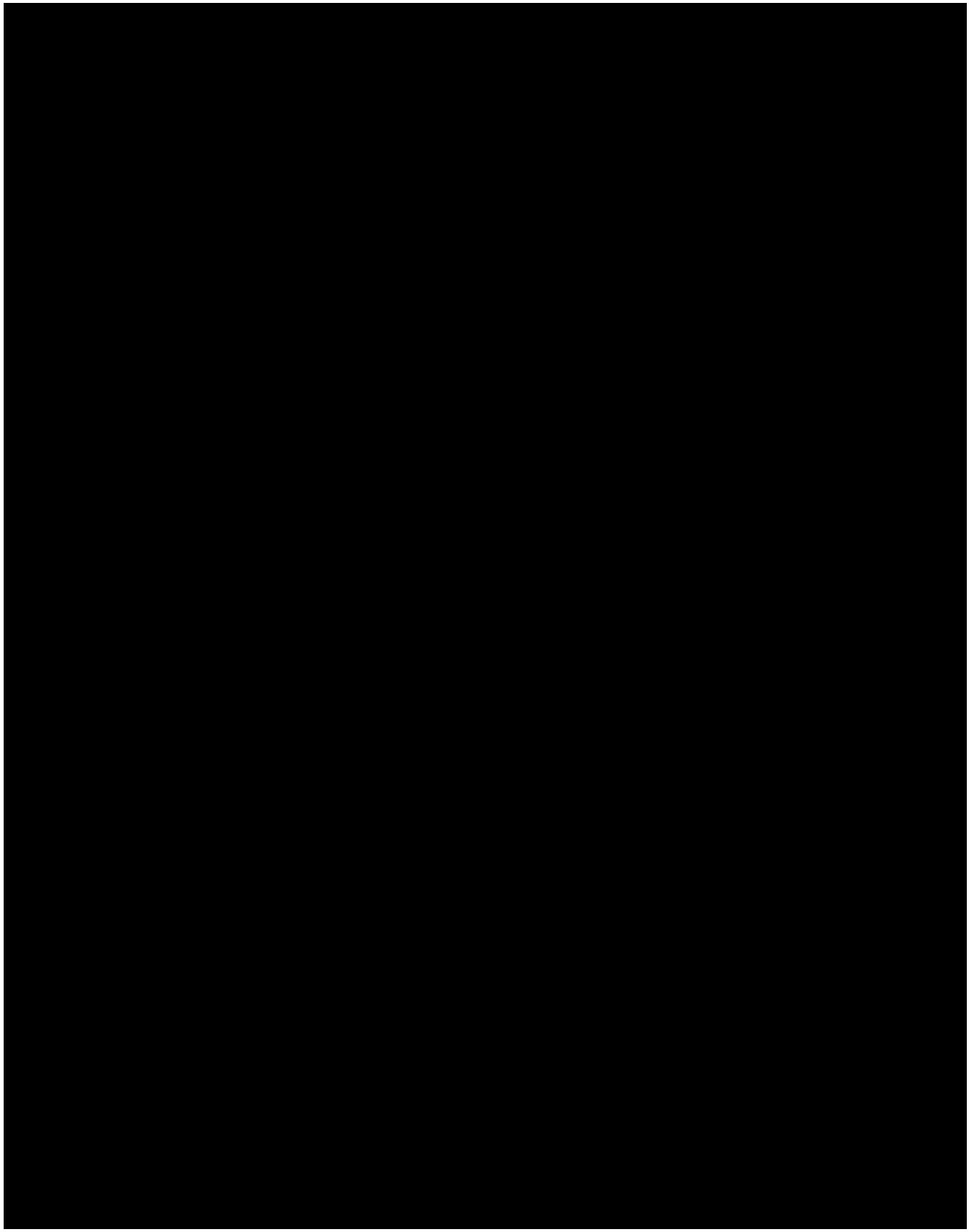












D. WALMART

Distribution Center	DEA Registration Number
DC 6045 (CIIs) Bentonville, Arkansas	RW0282145
DC 6028 Crawfordsville, Indiana	RW0165731
DC 6046 Williamsport, Maryland	RW0199908

From 2002 to April 2018, Walmart self-distributed Schedule II controlled substances from Walmart pharmacy distribution center – DC 6045 (DEA Registration # RW0282145) that was located at 1201 Moberly Lane, Bentonville, AR 72716 (until July 27, 2015), and then at 2250 N 8th Street, Suite 102-A, Rogers, AR 72756 (beginning July 27, 2015).[506]

From 2002 until April 2018 Walmart self-distributed Schedule III and IV controlled substances to its pharmacies in Lake and Trumbull Counties from Walmart pharmacy distribution center DC 6028 (DEA Registration # RW0165731), located at 801 Corda Boulevard, Crawfordsville, IN 47933, and DC 6046 (DEA Registration # RW0199908), located at 11121 Elliot Place, Williamsport, MD 21795.[507] In October 2014 when hydrocodone was re-classified as a Schedule II controlled substance all distribution of the re-classified products was transferred to DC 6045 in Arkansas.

Walmart pharmacies were also able to order controlled substances directly from McKesson.[508]

Transactional Data:[509]

Date Range: 2006-2014 (ARCOS)

Volume:

Lake[510]	Dosage Units	MME	Base Weight
Hydrocodone	3,127,000	12,272,089	12,272
Oxycodone	3,598,700	39,273,422	26,182

[506] *Walmart's Objections and Responses To Plaintiffs' (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants* (July 24, 2020).

[507] *Walmart's Objections and Responses To Plaintiffs' (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants* (July 24, 2020).

[508] Johnson Dep. 230:7-231, 241:20-242:8)Hiland 1/22/19 426:11-430:6

[509] WMT_MDL_000254857 - WMT_MDL_000254870.

[510] Report of McCann, Appendix 8.

Trumbull[511]	Dosage Units	MME	Base Weight
Hydrocodone	2,976,100	13,279,837	13,280
Oxycodone	1,136,000	15,451,873	10,301

1. **Court ordered SOMS Discovery Disclosure:**

- *Walmart's Objections and Responses To Plaintiffs' First Set of Requests for Production to Wal-Mart Inc.* (June 20, 2018)
- *Walmart's Objections and Responses To Plaintiffs' First Set of Requests Interrogatories to Wal-Mart Inc.* (June 20, 2018)
- *Walmart's Amended and Supplemental Objections and Responses To Plaintiffs' First Set of Interrogatories to Wal-Mart Inc.* (September 21, 2018)
- *Walmart's Amended and Supplemental Objections and Responses To Plaintiffs' First Set of Requests for Production to Wal-Mart Inc.* (September 21, 2018)
- *Walmart's Objections and Responses To Plaintiffs' (First) Combined Discovery Requests to Retail Pharmacy Defendants* (November 30, 2018)
- *Walmart Inc.'s Written Responses to Plaintiffs' Rule 30(b)(6) Notices to Walmart* (January 7, 2019)
- *Walmart Inc.'s Second Amended And Supplemental Objections and Respones to Plaintiffs' First Set of Interrogatories to Wal-Mart Inc.* (January 9, 2019)
- *Walmart Inc.'s Written Repsonse to First 30(b)(6) Ntoice Topic (k)(1) and Second Notice Topic 18 identifying the Bates number and effective date of the initial thresholds used as part o fthe Reddwerks enhancements.* (Email from T. Fumerton et al to M. Innes et al dated January 21. 2019)
- *Walmart Inc.'s Third Amended And Supplemental Objections and Respones to Plaintiffs' First Set of Interrogatories to Wal-Mart Inc.* (March 4, 2019)
- *Walmart Inc.'s Fourth Amended And Supplemental Objections and Respones to Plaintiffs' First Set of Interrogatories to Wal-Mart Inc.* (June 20, 2019)
- *Walmart Inc.'s Objections and Respones to Plaintiffs' First Combined Disocvery Requests to Dispensers* (January 1, 2020)
- *Walmart Inc.'s Objections and Respones to Plaintiffs' "Initial Disclosures" Requests* (January 1, 2020)
- *Walmart's Objections and Responses To Plaintiffs' Requests for Production of Documents to Walmart* (July 7, 2020).
- *Walmart's Objections and Responses To Plaintiffs' Requests for Production of Documents to Walmart (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants* (July 24, 2020).
- *Walmart's Objections and Responses To Plaintiffs' (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants* (July 27, 2020).

[511] *Id.*

- *Walmart's Objections and Responses To Plaintiffs' (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants* (July 27, 2020).
- *Walmart's Objections and Responses To Plaintiffs' (Second) Combined Track Three Interrogatories to Chain Pharmacy Defendants* (January 22, 2020).

2. SOMS Corporate Policy Disclosed to Identify Suspicious Orders.

a. Time Period Before 2011.

Prior to 2011, Walmart did not have a written Suspicious Order Monitoring System. As of November 2010, it had a "Controlled Substance Monitoring" policy in its Pharmacy Manual that provided for monthly "Control Drug Stock Exception Reports."[512] The Control Drug Stock Exception reports were forwarded monthly to the Arkansas DEA. This policy did not include a written Suspicious Order Monitoring system to monitor orders of controlled substances placed by its pharmacies for orders of unusual size, frequency or pattern. Instead, Walmart had an unwritten expectation that the employees in the Distribution Center "pickers" would notice if an order was an "outlier" or "seemed a little high."[513] According to Walmart, these associates were tasked with monitoring the orders that they were filling for unusual size, and alertinga supervisor if an order appeared unusual based on their experience and memory.[514] Walmart did not provide any guidance to these associates as to how they should flag an order as suspicious.[515] Instead, Walmart relied on these associates' own subjective personal experiences and memories.[516] When reviewing orders, these Walmart associates did not have access to and therefore could not consider prior orders of a particular pharmacy when determining whether to flag an order from that pharmacy for further review.[517] If an associate noticed an order that required further review, they were supposed to convey their concerns about the order and the order details verbally to managers at the Distribution Centers – there was no written correspondence about the unusual order. [518]

Walmart did not provide these associates with any training with respect to how to identify suspicious orders.[519] Moreover, carrying out Walmart's unwritten process for identifying suspicious orders was not the sole and primary task for these associates, but was in addition to

[512] WMT_MDL_000011106.

[513] Hiland 1/22/19 Depo., 170:17-171:5 and Abernathy Depo., 25:24-26:10.

[514] Hiland 1/22/19 Depo., 45:7-46:2 and 169:9-21; *see also*, Abernathy Depo., 24:15 – 25:6.

[515] Hiland 1/22/19 Depo., 214:7-22; 219:10-21.

[516] Hiland 1/22/19 Depo., 52:1-13; 170:17 – 171-6; and 215:18 – 216:23.

[517] *Id*. at 187: 12-17.

[518] *Id*. at 200:1-201:21.

[519] *Id*. at 219:10-21; Abernathy Depo., 40:11- 41:24.

their daily responsibilities of packing and shipping orders.[520] During this time period, DC 6045 associates were filling 700-800 orders of Schedule II controlled substances per day, four days per week.[521]

b. Time period 2011 to 2015.

From approximately 2011 until approximately 2014, Walmart did not have a written Suspicious Order Monitoring System. Walmart implemented a system to flag certain orders, but continued to ship flagged orders. The Reddwerks System – Walmart's warehouse inventory management software – flagged weekly orders for all drugs, including controlled substances of 50 bottles or more for any given National Drug Code Number ("NDC No.") for all Distribution Centers.[522] Reddwerks also flagged orders over 20 bottles for DC 6045.[523] Reddwerks also flagged orders that were 30% higher than a rolling 4-week average by NDC number so long as the order was for greater than 10 bottles of a single NDC No.[524] The orders for more than 20 bottles were flagged and the orders of more than 50 bottles were cut down to 50 bottles at the Distribution Centers.[525]

From approximately July 2012 until approximately 2015, Walmart implemented limited orders of Oxycodone 30mg ("Oxy 30") to no more than 20 bottles. Orders of Oxy 30 greater than 20 bottles were automatically cut to 20 bottles and shipped.[526] Also during this time a daily report was generated for all orders for Schedule II controlled substances greater than 20 bottles, which Walmart called "the Over-20 Report".[527] During this time period (extending back to 2010), Walmart continued to rely on the Distribution Center employees to manually identify "outlier" orders, to review the monthly Controlled Drug Stock Exception Reports and internally circulate reports listing all stores/times above 4% for further review.[528] However, Walmart testified that these reports were not used to identify potential diversion.[529]

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[520] Abernathy Depo., 24:15 – 25:6.

[521] Abernathy Depo., 40:11-21.

[522] Hiland 1/22/19 Depo. 266:7-12; 268:22-269:2.

[523] WMT_MDL_000009386 (10/29/14 PowerPoint Presentation "SOM Overview & Strategy").

[524] WMT Responses to Combined Discovery served 11/30/18 Request No. 2 and Hiland 1/22/19 Depo., 269:8-270:17.

[525] WMT_MDL_000009386(10/29/14 PowerPoint Presentation "SOM Overview & Strategy"); Hiland 1/22/19 Depo., 365:18-366:15.

[526] Hiland 1/22/19 Depo., 272:1-10 and 274:4-275:4.

[527] WMT Responses to Combined Discovery served 11/30/18, Request No. 2; Hiland 1/22/19 Depo., 274:4-275:4.

[528] WMT Responses to Combined Discovery served 11/30/18 Request No. 2.

[529] Hiland 1/22/19 Depo., 253.

As of August and September 2014, Walmart had written "Controlled Substances Suspicious Order Monitoring" policies in its Practice Compliance and "Evaluating Orders of Interest and Suspicious Order Reporting" policies in the Pharmacy Manual respectively.[530] Neither policy included the above flagging systems, but instead the policies described the levels of review for an (1) "Order of Interest: An order that warrants follow-up evaluation to determine whether it is suspicious" and (2) "Suspicious Order: An Order of Interest which has been evaluated and determined to be suspicious."[531] The policy anticipates that an Order of Interest may be held beyond the "expected shipment date."[532]

c. Time Period 2015 to November 2017.

In 2015 Walmart implemented "Reddwerks Enhancements", which were store-specific thresholds that flagged orders over a specific minimum that were also greater than three times the standard deviation of the specific pharmacy's order history for each controlled substance. [533]

In January and February 2015, Walmart edited its Controlled Substances Suspicious Order Monitoring policy in its Practice Compliance and "Evaluating Orders of Interest and Suspicious Order Reporting" in its Pharmacy Manual.[534] The changes included the addition of non-controlled substances and medical devices to the policies. More importantly, the policies anticipated that an "Order of Interest" could be "held beyond the expected shipment date" and it introduced an "Order of Interest Evaluation Form" for documenting "order of interest evaluations."[535] As of September 2013, Walmart had drafted an "Order of Interest" Investigation Protocol and "Order of Interest Investigation Form" as part of a "Controlled Substance Distribution Monitoring Program".[536] I did not see evidence, however, that ithis form was used. The determination of whether an Order of Interest was a Suspicious Order was to be made by "agreement of the Health & Wellness Director of Controlled Substances and the Senior Director of Pharmacy Logistics.[537] A December 2015 Pharmacy Manual "Evaluating Orders of Interest and Suspicious Order Reporting" was produced.[538] There were no material changes in the policy from the policy issued earlier in the year.

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[530] WMT_MDL_000008377 and WMT_MDL_000011107.

[531] *Id*.

[532] *Id*. at 11108.

[533] WMT Responses to Combined Discovery served 11/30/18 Request No. 2; Hiland Dep. at 312:7-18; Hiland Dep. at 403:24 - 404:5.

[534] WMT_MDL_000004237 and WMT_MDL_000000963.

[535] WMT_MDL_000000963 at 964.

[536] WMT_MDL_000009834.

[537] WMT_MDL_000000963.

[538] WMT_MDL_000000966.

In April 2017, Walmart amended the "Controlled Substances Suspicious Order Monitoring" in its Practice Compliance manual and amended its "Evaluating Orders of Interest and Suspicious Order Reporting" in its Health and Wellness Manual in June 2017.[539] The June 2017 amendments added reference to the "Quartiles IMS Suspicious Order Monitoring application." [540] The policy stated that the system would "identify controlled substances Orders of Interest and 'pend' (i.e. not ship, and hold for further review) those orders until a follow-up evaluation is completed."[541] Additionally, every Order of Interest was to be evaluated by the Pharmacy Logistics and Monitoring team. If the order was not cleared within 3 days, a report had to be sent to the Health & Wellness Director of Controlled Substances and the Vice President of Pharmacy Logistics. The amended policy also states that "Order of Interest evaluations should be documented in Archer using the Suspicious Monitoring Incident form."[542] The June 2017 manual amendents related to Walmart's decision to move from the Reddwerks system to the Buzzeo Suspicious Order Monitoring System which is addressed below.[543]

d. Time Period from Late 2017 until April 2018.

From late 2017 until approximately April 2018, Walmart used the Buzzeo SOM system to analyze orders from Walmart pharmacies and to flag "orders of interest." Every order the Buzzeo system flagged as being of interest was reported to the DEA.[544] The change from Reddwerks system to Buzzeo system for suspicious order monitoring included flagging orders before distribution and the creation of new thresholds.[545] As previously addressed, Walmart ceased self-distributing controlled substances in April 2018. The changes to Walmart's "order Evaluation Process" are illustrated in a PowerPoint presentation from 2017.[546]

3. <u>Enforcement Actions</u>

On February 15 2007, Walmart and the DOJ/DEA entered into a Settlement Agreement wherein Walmart agreed to pay a $120,000 fine. The settlement involved allegations that Walmart filled prescriptions for controlled substances under an incorrect DEA number, failed to include all required information on prescriptions, and filled prescriptions in the absence of a legitimate medical purpose.[547]

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[539] WMT_MDL_000004781 and WMT_MDL_000000969.

[540] WMT_MDL_000000969 at 970.

[541] *Id*. at 969.

[542] *Id*. at 971.

[543] Hiland 1/22/19, 386:23-387:8.

[544] WMT Responses to Combined Discovery served 11/30/18 Request No. 2.

[545] Hiland 1/22/19, 434:21-436:6.

[546] WMT_MDL_000048115.

[547] WMT_MDL_000043479.

On January 6, 2009, Walmart and the DOJ/DEA entered into a Settlement Agreement wherein Walmart agreed to pay a $637,000 fine and represented that it is taking good faith measures to detect and prevent diversion. The settlement involved allegations that Wal-Mart and Sam's Club Pharmacies negligently failed to make, keep or furnish records and reports, including invoices of controlled substances, and submission of DEA Forms 106.[548]

On March 11, 2011, Walmart and the DOJ/DEA entered into an Administrative Memorandum of Agreement wherein Walmart agreed to maintain a proper compliance program, make timely refusal to fill notifications to the local DEA, maintain policies and procedures to ensure that its pharmacies comply with all applicable laws, comply with all state and federal laws and regulations with regard to dispensing controlled substances, implement procedures to verify DEA registration number validity, make the records that it is required to keep pursuant to the CSA and implementing regulations available to DEA agents, submit dispensing records to PMPs with valid, active DEA registration number, allows and encourages its pharmacists to obtain and review a patient and/or doctor profile from the PMP, institute policies and procedures to block the early refill of controlled substances, install security cameras in all its Pharmacy locations that capture images of all transactions at the pharmacy counter, and report to the local DEA office the initiation of any official legal proceedings against it. The MOA involved allegations that improperly dispensed controlled substances, dispensed controlled substances for other than a legitimate medical purpose, and dispensed controlled substances that Walmart knew or should have known were being diverted.[549]

On May 15, 2015, Walmart and the DOJ/DEA, etc. entered into a Settlement Agreement wherein Walmart agreed to pay a $127,500 fine. The allegations against Walmart included Walmart submitted or caused to be submitted improper claims for payment to the Medicaid Program (Medicaid) and that Walmart negligently violated the relevant record keeping and reporting provisions.[550]

On August 31, 2015, Walmart and the DOJ/DEA, etc. entered into a Settlement Agreement wherein Walmart agreed to pay a $376,000 fine. The settlement involved allegations that certain Walmart and Sam's Club pharmacies filled prescriptions issued by individual practitioners who lacked a valid DEA registration number, and filled prescriptions issued by individual practitioners with a valid DEA registration number but used an invalid DEA registration number when recording and reporting the prescription.[551]

On December 22, 2020, the Department of Justice commenced a civil enforcement action in the U.S. District Court for the District of Delaware alleging that Walmart violated the CSA in

[548] WMT_MDL_00004384.

[549] US_DEA_0006101.

[550] WMT_MDL_000043497.

[551] WMT_MDL_000043507.

multiple ways as the operator of its pharmacies and wholesale drug distribution centers including by unlawfully dispensing controlled substances from pharmacies it operated across the country and unlawfully distributing controlled substances to those pharmacies throughout the height of the prescription opioid crisis.[552] "The result of a multi-year investigation by the department's Prescription Interdiction & Litigation (PIL) Task Force, the complaint filed in the U.S. District Court for the District of Delaware alleges that Walmart violated the CSA in multiple ways as the operator of its pharmacies and wholesale drug distribution centers. The complaint alleges that, as the operator of its pharmacies, Walmart knowingly filled thousands of controlled substance prescriptions that were not issued for legitimate medical purposes or in the usual course of medical practice, and that it filled prescriptions outside the ordinary course of pharmacy practice. The complaint also alleges that, as the operator of its distribution centers, which ceased distributing controlled substances in 2018, Walmart received hundreds of thousands of suspicious orders that it failed to report as required to by the DEA. Together, the complaint alleges, these actions helped to fuel the prescription opioid crisis. If Walmart is found liable for violating the CSA, it could face civil penalties of up to $67,627 for each unlawful prescription filled and $15,691 for each suspicious order not reported. The court also may award injunctive relief to prevent Walmart from committing further CSA violations."[553]

4. **Suspicious Orders Reported in CT3 Jurisdictions:**

2006: 0
2007: 0
2008: 0
2009: 0
2010: 0
2011: 0
2012: 0
2013: 0
2014: 0
2015: 0
2016: 0
2017: 0
2018: 0

5. **Opinions Related to Walmart**

   a. **Walmart failed to *maintain effective control* against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].**

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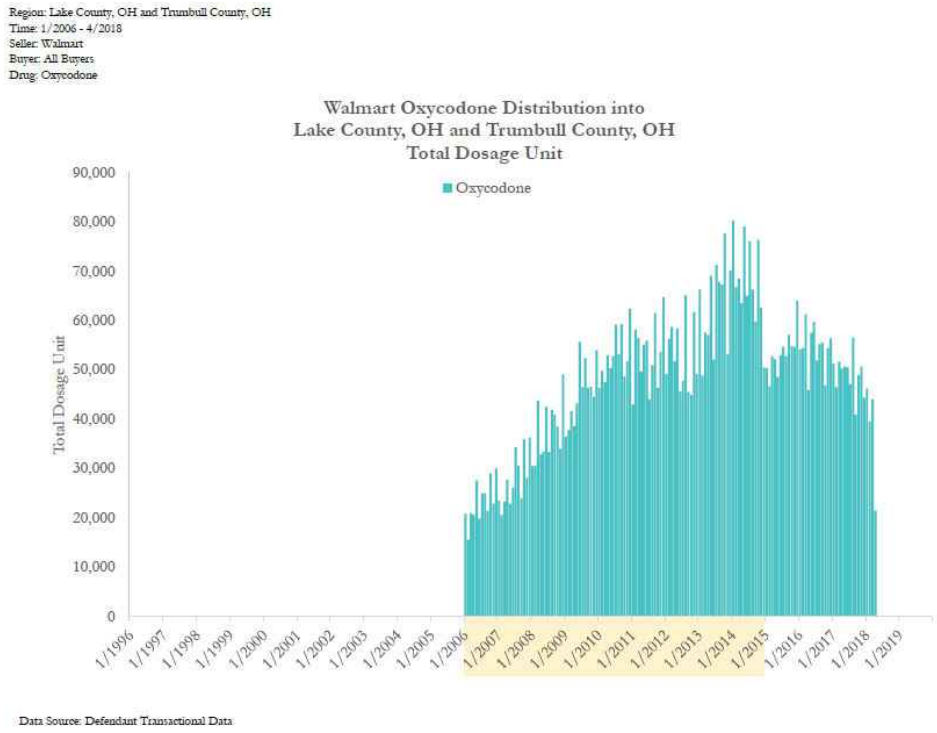
552 https://www.justice.gov/opa/pr/department-justice-files-nationwide-lawsuit-against-walmart-inc-controlled-substances-act (last visited April 16, 2021).

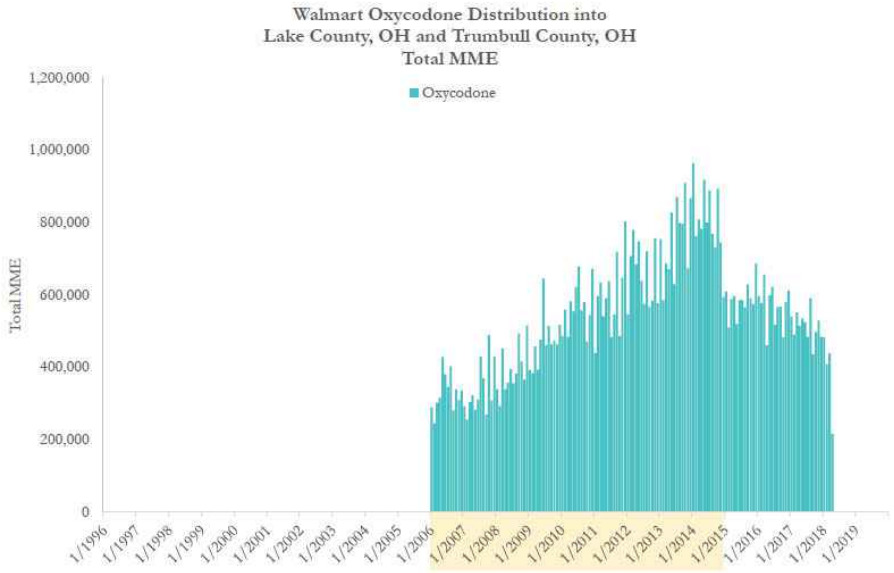
553 https://www.justice.gov/opa/pr/department-justice-files-nationwide-lawsuit-against-walmart-inc-controlled-substances-act (April 16, 2021).

The graphs below demonstrate a clear escalation of prescription hydrocodone and oxycodone by Walmart into Lake and Trumbull Counties.[554]



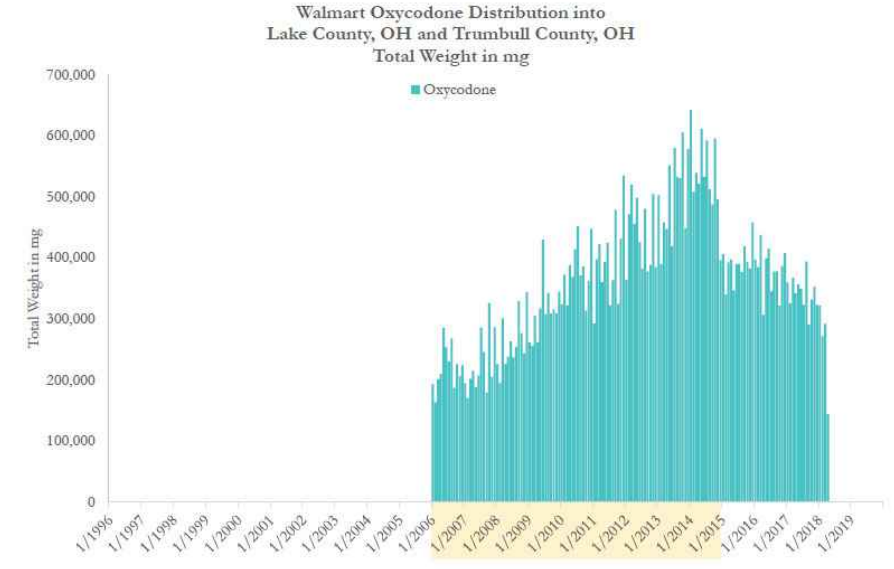
[554] Report of McCann, Appendix 9.

Region: Lake County, OH and Trumbull County, OH
Time: 1/2006 - 4/2018
Seller: Walmart
Buyer: All Buyers
Drug: Oxycodone



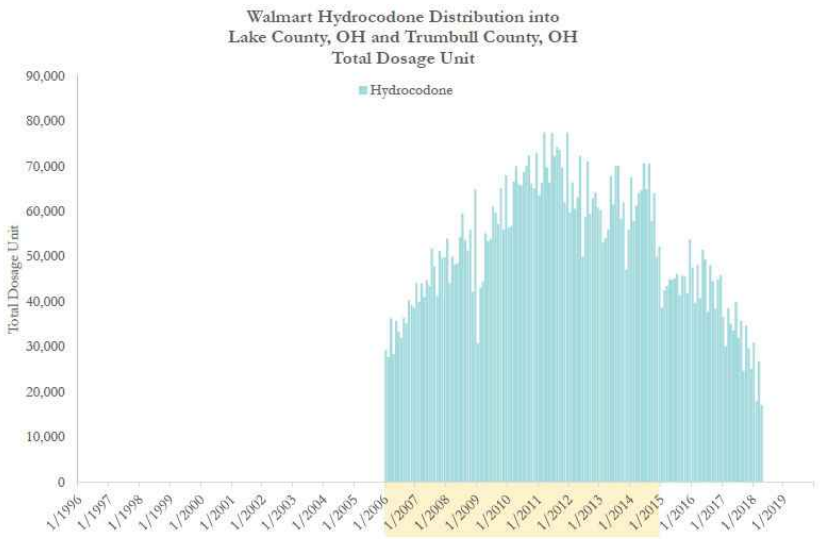
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 1/2006 - 4/2018
Seller: Walmart
Buyer: All Buyers
Drug: Oxycodone



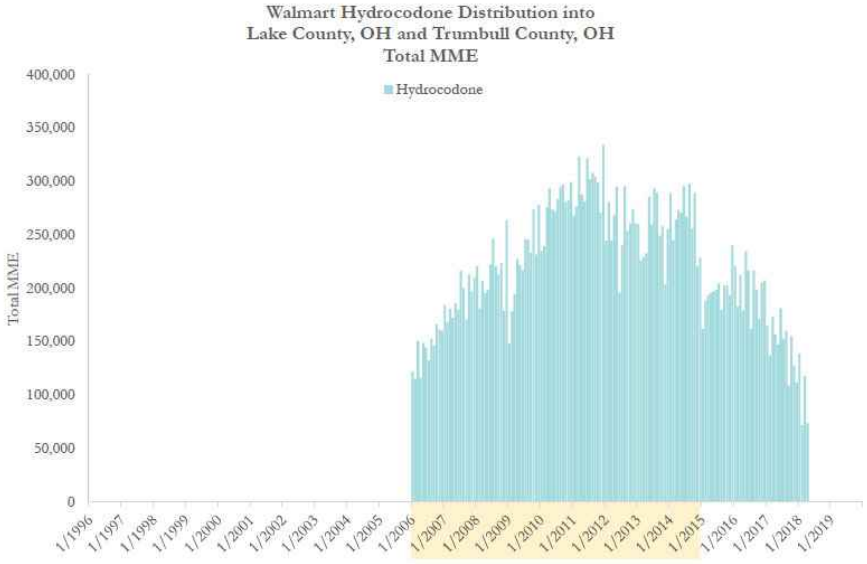
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 1/2006 - 4/2018
Seller: Walmart
Buyer: All Buyers
Drug: Hydrocodone

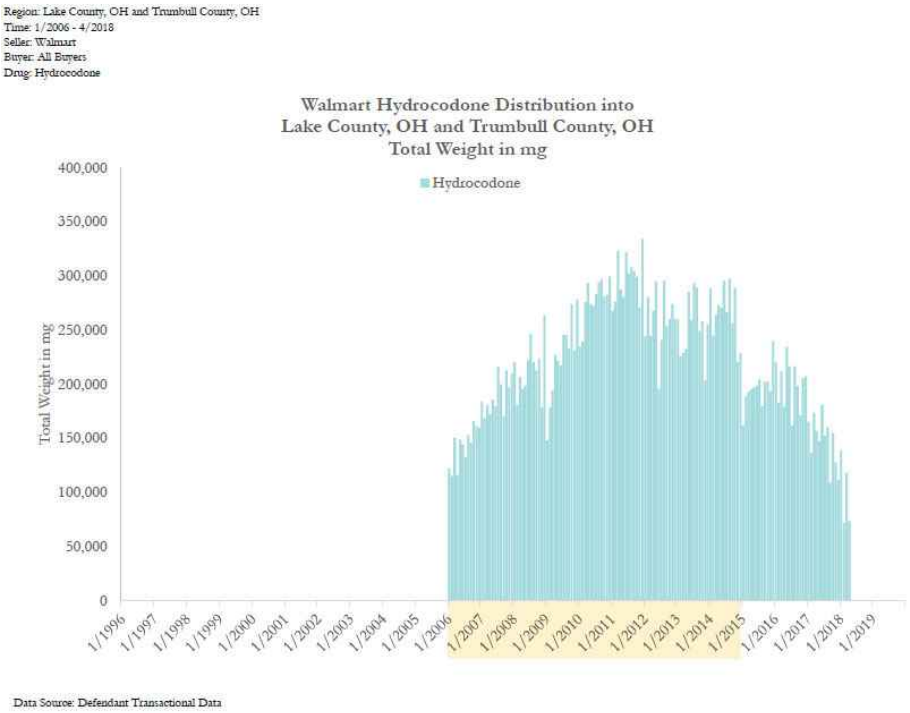


Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 1/2006 - 4/2018
Seller: Walmart
Buyer: All Buyers
Drug: Hydrocodone



Data Source: Defendant Transactional Data



In my opinion the massive increase in prescription opioids without sufficient due diligence documented is indicative of a failure to maintain effective control.

b. Walmart failed to design and operate a system to identify suspicious orders of controlled substances in violation of the security requirement set forth in 21 C.F.R. § 1301.74(b).

An overriding theme throughout the documents and testimony provided by Walmart is the decision to disregard its obligations and failing to maintain effective controls to prevent diversion under the CSA and to ignore the consequences of doing so. Jeff Abernathy was the Operations Manager at DC 6045 in 2006, the Operations Manager for all CII distribution in 2007, and Home Office Pharmacy Order Monitoring Team from 2016 to 2017.[555] Despite having oversight of all Schedule II controlled substances for Walmart, he testified that he was not aware that there was an opioid crisis in this country until he saw it on television during the 2016 presidential election.[556] The opioid epidemic was never mentioned in his presence at Walmart.[557] Additionally, Mr. Abernathy testified that he possessed neither adequate experience nor training when he was charged with determining which Schedule II orders were suspicious. Walmart provided him with no formal training and no written policies or procedures specific to Suspicious Order Monitoring.

[555] Abernathy Depo., 14:1-16.

[556] Abernathy Depo., 33:16-34:5.

[557] Abernathy Depo., 34:6-8; *see also* Sullins Depo., 96:5-97:9

Instead, he was left to rely on on-the-job experience working with Schedule II drugs and "just looking at orders and just, you know, if something looked unusual, then that's what I looked at."[558]

These deficiencies were not limited to DC 6045. According to Ed O'Brien, the Operations Manager at DC 6046 in Williamsport, Maryland, Walmart refused to devote adequate resources and personnel to properly evaluating orders that Walmart's SOM system had flagged for evaluation. As a result, DC 6046 chose not to review every flagged order. In a memorandum circulated on or about October 11, 2013, Mr. O'Brien stated that there were "too many orders to review each line [of Reddwerks orders alerts] in detail."[559] And, almost exactly a year later, Walmart "recognized that there is limited time for evaluation."[560] This willful ignorance at the administrative levels of Walmart is evidence of the lack of training, lack of policies, and lack of attention to the obligations imposed by law upon registrants responsible for distributing controlled substances.

I was not provided any documentary evidence that Walmart had an effective system in place to identify orders of unusual size, pattern, or frequency.[561] Instead, Walmart reports that its Distribution Center employees and associates – who were responsible for filling orders manually monitored the orders that they were filling to identify orders that were "outliers" or "seemed a little high."[562] There were no written policies or guidelines for what should be identified as something that seemed too high.[563] If the associates, upon review of the orders did identify something that seemed high, they were to report it to their supervisors.[564] The associates were provided no resources to determine if something should be reported to the supervisor. Instead, the hourly associates relied only on their experience and memory.[565] When reviewing orders, these Walmart associates did not consider prior orders of a particular pharmacy when determining whether to flag an order from that pharmacy for further review.[566] There was no policy in place to require the memorialization of the identification and communication about the unusual order.[567]

This manual process for identifying unusual orders was not their sole or primary task, but

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[558] Abernathy Depo., 94:5-95:15.

[559] WMT_MDL_000195036.

[560] WMT_MDL_000008076.

[561] WMT Responses to Combined Discovery Interrogatory NO. 2; Hiland Depo., 221:21-222:5, and 295:7-18 (referring to Controlled Drug Stock Exception Reports).

[562] Abernathy Depo., 24:15 – 25:6; 40:11 – 41:8.

[563] Abernathy Depo., 26:11-20.

[564] Abernathy Depo., 26:15-25.

[565] Hiland 1/22/19 Depo., 170:17-171:3; see also Abernathy, 24:15 – 25:6.

[566] Hiland 1/22/19, 187: 12-17.

[567] Hiland 1/22/19 Depo., 200:1-201:21.

was in addition to their daily responsibilities of packing and shipping orders.[568] The DC filled orders of controlled substances from more than 4,000 pharmacies over a four-day week.[569] Walmart also claims that if an associate alerted management regarding a particular order, the supervisor would investigate with the ordering store to ascertain whether the order was correct.[570] But I did not see any documentary evidence of this ever occurring. There was also no policy to hold an order during the pendency of any "investigation."[571] This manual approach of relying on the memory and experience of the employees picking, packing and shipping the controlled substances for all of Walmart's pharmacies was not an effective means of identifying, reporting and preventing the diversion of controlled substances.

As early as September 27, 2010, James Greer, Senior Asset Protection Manager of Walmart Pharmacy Distribution Centers alerted senior staff at Walmart, including Susanne Hiland, that "[t]he DEA expect[d] the DC's to have a 'more intimate relationship with its customers'. . . [and] that [the DEA] want[ed] the DC to be able to show due diligence."[572] Yet, that same year, Walmart's Senior Asset Protection Manager for Walmart Pharmacy Distribution Centers stated that the DEA "indicated more than once that they want the DC to be able to show due diligence … we do not have a 'flag' amount … All we have to do is show we are following it … we do not want to make the flag so high that it does not trigger, but we do not want to make it so low that it is flagging all of the time."[573]

From approximately 2011 until approximately 2015, Walmart used its warehouse inventory management system, Reddwerks, to flag weekly orders for pharmaceuticals, including controlled substances, of 50 bottles or more, as well as orders that were 30% higher than a rolling 4-week average for that item as long as the order was for more than 10 units of any given NDC No.[574] In practice, however, Reddwerks was not a suspicious order monitoring program, "rather Reddwerks, in a broad sense, is a warehouse management system . . . used for the picking environment . . . where order fillers pick an order."[575] Even so, Walmart used Reddwerks to set "order alerts"—sometimes known as "thresholds"—that would flag only orders over a certain quantity but did not hold or stop or pend the orders.[576] Walmart's documents acknowledge that

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[568] Abernathy Depo., 42:19-43:5.

[569] Sullins Depo., 56:6 – 57:5.

[570] Walmart Fed. R. Civ. P. 30(b)(6) Deposition Tr., 242:22-243:15.

[571] Hiland 1/22/19, 477:19-478:5.

[572] WMT_MDL_000057259.

[573] WMT_MDL_000057259.

[574] *See* WMT Responses to Combined Discovery 11/30/18, Interrogatory No. 2 and Hiland 1/22/18 Depo., 269:8-21; 270:7-17.

[575] Ducote Depo., 89:20-23.

[576] WMT_MA_000001623 (Pharmacy Manual 21/402 explains Reddwerks order alerts)

the Reddwerks system only flagged or identified orders of "unusual size."[577] It did not flag or identify order of unusual pattern or frequency.

In mid-2012 Walmart implemented a policy of limiting Oxy 30 orders to no more than 20 bottles.[578] In July, 2012, a series of e-mails detail the directions from Walmart's Bentonville, Arkansas office directing the creation of a "Max limit of 20 bottles for only Oxycodone 30mg at this time."[579] Under this policy, weekly orders of Oxy 30 were automatically cut to 20 bottles per store per week (for example, a 40-bottle order was cut to 20 bottles).[580] On July 23, 2012, a list was circulated that included several Walmart pharmacies placing orders well in excess of 20 bottles of Oxycodone 30mg and Oxyco/APAP 5/325.[581] Only 2 of the stores listed had their orders cut to 20 bottles before shipping.[582] In a mid-August 2012, e-mail to "Replen Pharmacy," Walmart's Divisional Replenishment Manager, Bart Grisham, voiced concerned that Walmart's "CII warehouse license could be injeopardy" because of the volume of Oxy 30 being shipped to individual stores.[583] A limit of 3 bottles per day per order of Oxycodone 30mg and Oxycodone HCL 30mg were put in place.[584] In an October 14, 2013 email, Mr. Abernathy stated that DC 6045—which was the only Walmart distribution center that distributed oxycodone 30mg—had a "standing" cut for Oxycodone 30mg and that "[a]ny order over 20 bottles of this item is cut back to 20 bottles."[585] Reduced, or cut, orders were neither reported to the DEA, nor held until determined to be appropriate (i.e., the orders shipped).[586] Walmart disregarded the limit and shipped well over 20 bottles of Oxy 30 to its own pharmacies.[587]

During this time period Walmart also monitored orders of over 20 bottles for controlled substances other than Oxy 30 and created Over-20 Reports.[588] The Over-20 Reports were supposedly reported to the Home Office for review before shipping by the managers at DC 6045 on a daily basis. While there is evidence of these daily reports being provided to the Home Office for further review, there is no evidence of any review or any action taking place at the Home Office

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[577] WMT_MDL_000009386.

[578] WMT_MDL_0000009319.

[579] WMT_MDL_0000009319.

[580] WMT_MDL_000009319; WMT_MDL_000009386.

[581] WMT_MDL_000009321 at 000009322.

[582] WMT_MDL_000009321 at 000009323.

[583] WMT_MDL_000011949.

[584] *Id*.

[585] WMT_MDL_000009872.

[586] Abernathy Depo., 64:25 – 65:22.

[587] WMT_MDL_000042877; WMT_NM_AG_000001486; WMT_NM_AG_000000044; WMT_NM_AG_00000153.

[588] WMT Responses to Combined Discovery served 11/30/18, Request No.2.

prior to shipping. Mr. Abernathy who was at times the Operations Manager at DC 6045, testified that he never recalls the Home Office reviewing or holding any order and that these orders that were sent for review would routinely be shipped the same day if he did not hear from the Home Office.[589] More specifically, the Over-20 Report was provided to the Home Office in the morning, and if nothing was done by mid-afternoon, the orders were filled and shipped.[590] He could not recall one instance over the four to five years that he prepared these reports when an order was reviewed or even held. [591] Further, if an order was reduced, the ordering pharmacy could place an order through McKesson or Amerisource Bergen.[592] The evidence suggests that Walmart did not follow its own policies as multiple "Over 20 Reports" indicate instances in which greater than 20 bottles of oxycodone 30mg were shipped.[593] In fact, Kristy Spruell, Senior Manager for Logistics, testified that for a period of time between June 2013 and July 2015, compliance personnel working in the Home Office were not involved in detecting suspicious orders, and "any decisions that needed to be made were being left to the distribution center…."[594] This inherent flaw made it impossible for Walmart to fulfill its obligation to maintain effective controls for the revention of diversion under the CSA.

From approximately 2010 until 2015, Walmart claims that employees in distribution centers reviewed the SD405 reports and internally circulated reports listing all stores/items above 3.99% (referred to as "4% reports") for further review and follow- up as needed.[595] Specifically, these 4% reports listed any controlled substance ordered by any store that was over 3.99% of the store's total orders for a given month. The 4% reports were internally circulated for further review and investigation.[596] Walmart's SD405 report was issued separately for each pharmacy distribution center on a *monthly* basis, and identified controlled substances shipped to Walmart's pharmacies during the prior month broken down by item (SD405-1 report) and by store (SD405-2 report). Walmart's corporate designee testified that SD405 reports were not used by the DC 6045 associates to assist in determining if an order was suspicious.[597] Abernathy did not remember ever seeing this report.[598] Furthermore, as used by Walmart, SD405 reports could not prevent against diversion.

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[589] Abernathy Depo., 59:6 – 61:21.

[590] Abernathy Depo., 59:6 – 61:21.

[591] Abernathy Depo., 61:14-21; 122:24 -123:23; and 138:1-7.

[592] Abernathy Depo., 254:2-10.

[593] WMT_MDL_000009319; WMT_NM_AG_000001486; WMT_NM_AG_000000044; WMT_NM_AG_00000153

[594] Spruell Depo., 137:11-18.

[595] WMT_MDL_000011106 (PM 21-402).

[596] WMT_MDL_000009437.

[597] Hiland 1/22/19 Depo., 221:22 - 222:5 and 294:13 - 295:18

[598] Abernathy Depo., 69:17

1. Walmart acknowledged that the pre-2015 systems were deficient.

Walmart was certainly aware of the significant holes in the system used to identify, stop and report suspicious orders. The deficiencies were built into the systems that Walmart created for itself. For example, using NDC Nos. instead of families of drugs was wholly ineffective at identifying how many of any particular family of opioid was being ordered by any particular pharmacy. Walmart also knowingly allowed its pharmacies to order drugs directly from McKesson thereby exceeding even what Walmart called "hard limits" imposed and allowing a means of bypassing an already deficient system. And until late in 2015, no attempt was made to identify suspicious orders until *after* they were already shipped.

The practice of receiving an order, reducing the quantity of the order, and shipping that reduced quantity without reporting the order as suspicious to DEA failed to maintain effective controls to prevent diversion and circumvented 21 C.F.R. § 1301.74(b). Additionally, as early as September 27, 2010, during an audit at DC 6013, the DEA told Walmart that DEA wanted to see Walmart's "due diligence in dealing with excessive or suspicious orders."[599]Indeed, in August 2014 Kristy Spruell, instructed that "[i]t is critical that we do not ship any part of a "suspicious" order, so the functionality to hold an order pending evaluation is absolutely required. 'Cutting' an order should only be any option if the orders is an error (e.g. store intended to order 10 bottle, ordered 100)."[600]

On November 13, 2013, Shelley Tustison, Senior Manager, Corporate Compliance, circulated a "Controlled Substance Risk Assessment Executive Summary." The third page of that document says "Suspicous order Identification, Monitoring, and Reporting. Design & operate a systems (sic) to detect suspicious orders and report to the DEA when discovered."[601] The delivery status of that project is listed as "TBD" (To Be Determined).[602] This is consistent with other Walmart documents from this time period.[603] In other words, two years after the 2011 MOA with the DEA that reiterated Walmart's obligations under the CSA, Walmart still had neither desgined, nor operated a system to detect suspicious orders and report the suspicious orders to the DEA when discovered.

In February 2014, Mu Sigma, an outside consultant that advised Walmart about the development of its SOM program, informed Walmart that it could revise that program to detect Walmart pharmacies' unusual ordering patterns and combinations, which could indicate that a

[599] WMT_MDL_000057259.

[600] WMT_MDL_000028599.

[601] WMT_MDL_000053024.

[602] WMT_MDL_000053024.

[603] WMT_MDL_000062668.

particular Walmart pharmacy was dispensing dangerous drug "cocktails."[604]

A June 2014 document titled "Portfolio Scoring Worksheet, Suspicious Order Monitoring" is telling. [605] The worksheet is a series of questions with a corresponding answer in the form of a numerical score. Walmart's internal document acknowledges that it "has no process in place" for "Suspicious Order Monitoring" and, as a result, "the events or condition underlying the risk" (inability to identify and report suspicious orders of controlled substances) is "likely" to occur. Walmart acknowledges that its failure to have a system in place violates a "national" legal and regulatory requirement, and that is related to a "settlement or agreement with a Government Agency." And, finally, the Board of Directors was "informed" of this risk.[606]

In an email dated August 27, 2014, Kristy Spruell, Senior Manager for Logistics, advised that "'[c]utting' an order should only be an option if the order is an error (e.g. store intended to order 10 bottles, ordered 100)." (Emphasis added.)[607] In an internal email dated November 5, 2014, concerning the use of "error" as a reason code for cutting orders, Jeff Abernathy wrote: "Many things could be considered an 'error' other than just mis-keying an order. Such as, due to the change of Hydro to a CII some pharmacist[s] feel the need to stock up. The company feels 50 bottles is enough and pharmacist shouldn't stock up, thus an error in decision making. And many other reasons not confined to miskeying."[608]

In September 2014, Walmart's internal email discussions regarding the Verified Accredited Wholesale Distributors ("VAWD") accreditation process acknowledge that Walmart's SOMs did not have the ability to hold Orders of Interest.[609] Indeed, Walmart's internal documents and correspondence, as well as Walmart's direct interaction with VAWD, evidence repeated attempts to delay the inspection process because Walmart knew that its SOM system could not meet the VAWD standard.[610] "We received an extension from VAWD, but no additional extensions will be provided. According to the note below, should we fail to respond by September 29th, we may lose our accreditation. If we lose our accreditation, we will be unable to ship product. To meet this deadline, we need to have alignment on the interim SOM processes as quickly as possible. We are meeting with Jim on Wednesday, and we really need to come away from that meeting aligned and committed to a solution so that we have time to implement the interim solution before our corporate visit." [611]

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[604] WMT_MDL_000009852 (Mu Sigma "roadmap" email).

[605] WMT_MDL_000048100 - WMT_MDL_000048101.

[606] WMT_MDL_000048100 - WMT_MDL_000048101.

[607] WMT_MDL_000016257.

[608] WMT_MDL_000016313.

[609] WMT_MDL_000139199.

[610] WMT_MDL_00007305 (VAWD notice of reaccreditation); WMT_MDL_000016690) (request for extension to submit documents supporting VAWD accreditation); WMT_MDL_000016632).

[611] *Id.*

In a September 17, 2014 e-mail regarding a DEA inspection of Distribution Center 6028, James Langman noted that the DEA was asking about "our SOMP program for controlled substances in the DCs…several existing deficits could be a point of contention. The main deficit is that we don't have an automated process to identify and stop a suspicious order before shipping."[612] This is a fundamental activity to maintain effective controls to prevent diversion and essential for an effective Suspicious Order Monitoring System, the absence of which rendered Walmart's SOM program ineffective.

On October 16, 2014, an e-mail sent by Jeff Abernathy at DC 6045 detailed the same suspicious order monitoring issues that were encountered by the DEA in the days leading up to the September 17 e-mail from Langman.[613] Abernathy started with "Let's talk about Hydro! … Before Hydro an Over 20 report on a heavy day would be about 50 lines (item/store combo). Monday the report was 600 lines."[614] Abernathy explained that pulling the information from the database slowed the vault production. He asked for suggestions and offered the following:

- "I will still run the report to list all item/store combinations over 20 bottles."
- "I will continue to research and cut all Oxycodone 30mg orders over 20 bottles."
- "I will research all orders over 50 bottles and/or unusual orders."
- "I will highlightall orders that were cut." [615]

The attached spreadsheet was for Schedule II controlled substances that had a date of distribution of October 15, 2014. A review of the spreadsheet indicated there were 56 orders of Schedule II drugs that exceeded the order limit of either the Over 20 or Over 50. Four (4) orders exceeded the Over 50 limit and were cut to 50 and shipped. Fifty-two (52) orders exceeded the Over 20 limit and they were all shipped at the amount that was ordered.[616]

In an October 29, 2014 Walmart presentation entitled "SOM Overview & Strategy", it appears as though orders over 50 bottles were cut to 50 bottles, orders for more than 20 bottles of a CII item were flagged and reported but not cut.[617] In the same presentation, Walmart acknowledged the following areas for improvement in the SOMs program:

- Large number of false positives because thresholds aren't based on statistical methodology.

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[612] WMT_MDL_000054651.

[613] WMT_MDL_000009807.

[614] *Id.*

[615] *Id.*

[616] *Id.*

[617] WMT_MDL_000009386.

- Flags only identify "unusual size."
- McKesson orders are not considered in evaluation.
- All flags must be cleared before production on any items can begin, so there is limited time for evaluation.
- No defined process for tracking why DC cuts or clears specific orders.

Despite knowledge of all of these deficiencies, Walmart still did not implement changes to bring their SOMs into compliance.

In November 2014, Walmart acknowledged again that its systems ignored shipments of controlled substances that its pharmacies were also receiving from independent distributors. Walmart noted that "McKesson orders are not considered in evaluation." Likewise, the "Overview of SOM Project Progress" attached to a November 23, 2014 email stated that Walmart had "[n]o process for including McKesson orders in evaluation."[618]

A January 8, 2015 memorandum regarding FY 2016 (calendar year 2015) Compliance Objective 18 stated that the the system that "flagged all orders based on quantity limitations (order over 50 units), regardless of drug type," "lacked an efficient and consistent system to identify and present distribution of controlled substance suspicious orders."[619] A Health & Wellness compliance project titled "Suspicious Order Monitoring-Hard Limits" that sought to "create a stop to prevent a store from ordering over a certain threshold of controlled substances and aggregate vendor controlled substance order data with Walmart DC controlled substance order data for purposes of threshold order alerts" had not been started in August 2015 because Walmart had "no resources/capacity to start new projects" and was "planning to start in Q3 or Q4." The Suspicious Order Monitoring program ranked only 17 on Walmart's list of U.S. Compliance priorities. [620]

In a December 2015 presentation titled "Three Year Strategy HW Practice Compliance", Walmart summarized the "Program Evolution" acknowledging that it had "***No SOM process***".[621] The presentation also acknowledges Walmart had "No Controlled Substance analytics," and "No Controlled Substance risk management." Later in the presentation, Walmart set FYE 2017 (calendar year 2016) as the date to implement Buzzeo. Buzzeo, however, was to rolled out until November of 2017.[622]

As late as April 2016, Walmart knew that the system in place did not identify suspicious orders. In an e-mail from Mr. Abernathy, he reported an order the prior week for "55 bottles of

[618] WMT_MDL_000008076;WMT_MDL_000009159.

[619] WMT_MDL_000067539.

[620] WMT_MDL_000016772.

[621] WMT_MDL_000365540 (emphasis added).

[622] WMT_MDL_000365540.

the hydro 10/325. This should have alerted SOM but didn't".[623] The over 50 bottle alert was cleared as "there were more than 50 bottles in this order. What I think happened is: When we designed CSOS, I think we put in some programming to alert us when there was more than 50 bottles of an item ordered. Not so much for SOM but to make sure the store wanted that amount since we didn't do CII returns… If it alerted we would call the store to verify they wanted that amount then clear the alert and send the desired amount. "[624] Abernathy concluded "I feel this older programming might be skirting the SOM process in certain situations."[625]

An April 20, 2017 PowerPoint presentation listed as "yellow" (i.e. not complete) the overall status of a Walmart's project, owned by Miranda Johnson, to design and operate a system to detect suspicious orders of controlled substances and report them to the DEA when discovered.[626]

i. From 2015 through November 2017, Walmart implemented store-specific thresholds but did not otherwise change its systems.

In 2015 Walmart implemented store-specific thresholds Walmart termed "Reddwerks Enchancements."[627] These thresholds, which were based on a formula developed by a third party consulting firm, flagged only orders that were three standard deviations of a specific pharmacy's order history for each controlled substance.[628] By design, three standardard deviations above the mean would mean that less than 1% of orders triggering the threshold. Interestingly, Miranda Johnson, Director of Controlled Substance Compliance, stated she was not aware of the impact of applying the three standard deviations.[629] Walmart conceded that the minimum thresholds were set for business purposes rather than for use in maintaining effective controls against diversion as required by the CSA.[630]

Walmart was setting minimum thresholds for pharmacy orders before triggering a flag – that is, order amounts below which no orders were flagged under any circumstance regardless of size, pattern or frequency.[631] An example of this problem is clear upon review of Walmart's "Methodology for Flagging Store Orders" "for stores with a calculated minimum threshold lower

[623] WMT_MDL_000215753.

[624] *Id.*

[625] *Id.*

[626] WMT_MDL_000143356.

[627] Hiland 1/23/19 Depo., 312:7-18

[628] Reed Depo., 33:1-11; 35:5-23 and 37:23-38:8

[629] Johnson Depo., 99:22

[630] Hiland Depo., 403:24-404:5

[631] *Id.*

than 1764, the threshold is fixed at 1764."[632] The data for Store 3066's Oxycodone APAP 5/325 is an illustration.[633] The store has an average of "non zero" orders of 149. A standard deviation calculated as 119. Three times the standard deviation would be 358. Once 149 is added to the standard deviation of 358 the total threshold would be 507. 507 would represent more than 99% of all orders, yet Walmart assigned an arbitrary minimum threshold. By August 23, 2015, the Reddwerks enhancement thresholds showed the threshold for store 3066 for Oxycodone APAP 5/325 was 2000 bottles.[634] Under either calculation, this is not an effective means of identifying suspicious orders.

Walmart's corporate designee conceded that these minimum thresholds were set for business purposes,[635] as opposed to the "maintenance of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C.A. § 823(a)(1), (b)(1). For almost all pharmacies, the minimum amount to trigger a flag was 2,000 dosage units per week.[636] Accordingly, even when Walmart implemented a store-specific policy that took into consideration a pharmacy's order history, the program was still deficient because a pharmacy could, for example, go from ordering ten dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged, investigated or reported.

These thresholds were based on the standard deviation of a specific pharmacy's order history for each controlled substance.[637] In the lead up to the transition to the store-specific thresholds, Walmart acknowledged that its then current SOM program needed to be changed to avoid DEA enforcement.[638] On March 11, 2015, Ms. Johnson wrote the DEA to provide a written overview of these "enhancements."[639] Ms. Johnson chose not to disclose that Walmart's SOM contined to include minimum amounts below which no orders were flagged under any circumstance regardless of pattern or frequency.[640]

ii. Time Period from November 2017 until April 2018.

From November 2017 until approximately April 2018 (when Walmart ceased distribution of controlled substances), Walmart used the Buzzeo SOM system to analyze orders from Walmart

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[632] WMT_MDL_000009629 at 000009230.

[633] WMT_MDL_000009629 at 000009630 (attached spreadsheet)

[634] WMT_MDL_000042877, row 109801.

[635] Hiland 1/22/19 Depo., 403:24 - 404:5.

[636] These minimum thresholds were specific to the unique DEA numbers, so a store could order 8000 dosage units each of Oxy 5, 10, 30, etc. and never have an order reviewed, held, or reported.

[637] See WMT Responses to Combined Discovery 11/30/18 Interrogatory No. 2; Hiland Dep. at 312:7-18; Hiland Dep. at 403:24 - 404:5.

[638] WMT_MDL_000046593.

[639] WMT_MDL_000016910.

[640] WMT_MDL_000046593.

pharmacies and flag "orders of interest."[641] Buzzeo gave Walmart the ability to set alerts based on drug families as opposed to only looking at individual drugs. Before the implementation of the Buzzeo system, Walmart "could not identify concerns based on orders of multiple drugs from the same family."[642]

Walmart knew that once it switched to Buzzeo the alerts would dramatically increase because, among other things, orders would finally begin to be reviewed by active ingredient instead of by individual NDC number.[643] Walmart was aware that its SOM system prior to Buzzeo had this significant deficiency. In fact, as George Chapman, Senior Director, U.S. Erhics and Compliance Health and Wellness Practice Compliance, explained to George Riedl on October 31, 2017, "The other note around Size, Frequency and Pattern is that under the old system (Reddwerks) we had thresholds based on each NDC number and not drug strength. This means that someone could order Hydro/Apap 500/325 from 5 different NDC numbers and that would not create an alert. Under Buzzeo, we now would see that as an order of interest."[644] This loophole in the SOM system was certainly known to Walmart prior to this October 2017 e-mail. Walmart knew that it should have been considering drug families at least as early as July 2013 as evidenced by an e-mail forwarded to Kristy Spruell that explains "So for example store 2666 requested 5 different types of Oxy product for 82 bottles. They would not show on the 20+ report because they are under threshold."[645] Indeed, until Buzzeo, Walmart "could not identify concerns based on orders of multiple drugs from the same family."[646] Once it finally adopted Buzzeo, Walmart's SOM employees were overwhelmed by the number of orders that were being alerted for further review.[647] Soon thereafter, Walmart stopped self-distributing controlled substances.

6. <u>Due Diligence Conducted:</u>

Walmart did not report any Suspicious Orders to the DEA. Therefore, there were no due diligence files associated with suspicious orders for review. Additionally, the due diligence almart identified was extremely limited and did not represent maintanence of effective controls for the prevention of diversion under the CSA.

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[641] Walmart defines "order of interest" as "an order that warrants follow-up evaluation to determine whether it is suspicious." *See*, WMT Responses to Combined Discovery, citing WMT_MDL_000011107-11109.

[642] WMT_MDL_000138510.

[643] WMT_MDL_000141298.

[644] WMT_MDL_000018943.

[645] See, WMT_MDL_000028836 (acknowledging that looking at all oxy products ordered by a store is a more accurate depiction of store ordering than the over 20 report that looked only at a single product); see also WMT_MDL_000020332.

[646] WMT_MDL_000138510.

[647] WMT_MDL_000021115.

7. Shipping Requirement

Based on my review of the documents and testimony, orders were shipped and not held regardless of the size of the order. It was not until late 2014 that Walmart's written policies and procedures acknowledged that an order could be held until it was verified as appropriate.[648] However, there was no capability to hold an order pending review until 2015.[649] A March 2015 DEA audit of DC6028 did determine that "5 orders had shipped that were found to be suspicious."[650] Walmart's approach to cutting and shipping or simply shipping over threshold orders is a clear violation of the requirement that suspicion surrounding an order must be cleared before the order can be shipped. As no suspicious orders were reported in Lake or Trumbull Counties I cannot say whether Walmart shipped any order to Lake or Trumbull Counties that it identified as suspicious. However, I can say that Walmart did ship suspicious orders that should have been identified as requiring due diligence to determine whether the suspicion could be cleared to allow the order to be shipped.

E. Giant Eagle / HBC Service Company

Distribution Centers: HBC Facility, 601 Meadowlands Blvd., Washington, PA 15301
GERXDC Facility, 2500 Lovi Road, Freedom, PA 15042

DEA Registrant Numbers: RH0389773 (Washington)

RG0491047 (Freedom)

Transactional Data:

Date range: 2006-2014 (ARCOS)

Volume:

Lake[651]	Dosage Units	MME	Base Weight
Hydrocodone	3,544,400	13,700,367	13,700
Oxycodone	0	0	0

Trumbull[652]	Dosage Units	MME	Base Weight
Hydrocodone	7,443,700	32,896,579	32,897

[648] WMT Responses to Combined Discovery Interrogatory No. 2; WMT_MDL_00005465; WMT_MDL_000011107-11109.

[649] Hiland Depo., 477:19 – 478:5.

[650] WMT_MDL_000038273

[651] Report of McCann, Appendix 8.

[652] *Id.*

Oxycodone	0	0	0

Giant Eagle self-distributed prescription opioids to its pharmacy stores through two distribution centers: the HBC Services Company DC and GERX DC. Giant Eagle first self distributed opioids in 2009 through its HBC Service Company distribution center. HBC Service Company was a distribution center and a subsidiary of Giant Eagle, which was licensed as a distributor of controlled substances until October 2009 and did not begin distributing controlled substances until November 2009. HBC was limited by its DEA Registration to Schedule III- V controlled substances, and only distributed to Giant Eagle stores, which are wholly owned by HBC's parent company Giant Eagle. The only relevant Schedule III Opioids that HBC distributed were Hydrocodone Combination Products ("HCPs"), which were reclassified by the DEA as Schedule II controlled substances in October 2014. HBC stopped distributing HCPs when they were reclassified as Schedule II.[653]

Giant Eagle then opened the GERXDC, through which it self-distributed Schedule II-V prescription opiates to its pharmacy stores.[654] The GERX DC began distributing controlled substances, including prescription opiates, to Giant Eagle stores in February 2016.

1. **Giant Eagle / HBC Written Discovery Disclosures:**

- *HBC Service Company's Responses and Objections to First Notice of 30(B)(6) deposition* (07.26.2018)
- *HBC Service Company's Responses and Objections to Second Notice of Deposition Pursuant to 30(b)(6)* (07.26.2018)
- *HBC Service Company's First Amended Response to Plaintiffs' (First) Set of RFPs* (12.29.2018)
- *HBC Service Company's Second Amended Responses to Plaintiffs' (First) Combined Discovery Requests* (02.13.2019)
- *HBC Service Company's Written 30b6 Response to Plaintiffs' 2d Notice of Depo* (03.04.2019)
- *HBC Service Company's Second Supplemental Response to Plaintiffs' (First) set of Interrogatories* (03.29.2019)
- *GE + HBC First Amended Responses and Objections to P's (First) Combined Track 3 Interrogatories* (08.12.2020)

[653] Giant Eagle Distribution 30(b)(6) deponent, (12/13/18) Tsipakis Depo.73:24-74:8.

[654] Tsipakis Depo., 80:11-81:14.

- *GE + HBC First Amended Responses and Objections to Pls' (First) Combined Track 3 RFPs* (08.12.2020)

- *GE + HBC Responses and Objections to Plaintiffs' (Second) Combined Track 3 Interrogatories* (01.22.2021)

- *GE + HBC Answers and Objections to 30(b)(6) Topics 3-9 in Plaintiffs' Notice of Deposition* (02.22.2021)

- *GE + HBC Answers and Objections to 30(b)(6) Topics 8, 9, 11, and 12* (03.15.2021)

2. SOMS Corporate Policy Disclosed:

Giant Eagle's various SOM Programs are described in my opinions, set forth below in other areas of this report.

3. Enforcement Actions:

No DEA enforcement actions found for Giant Eagle or HBC.

4. Suspicious Orders Reported In CT3 Jurisdictions:

2009: 0

2010: 0

2011: 0

2012: 0

2013: 0

2014: 0

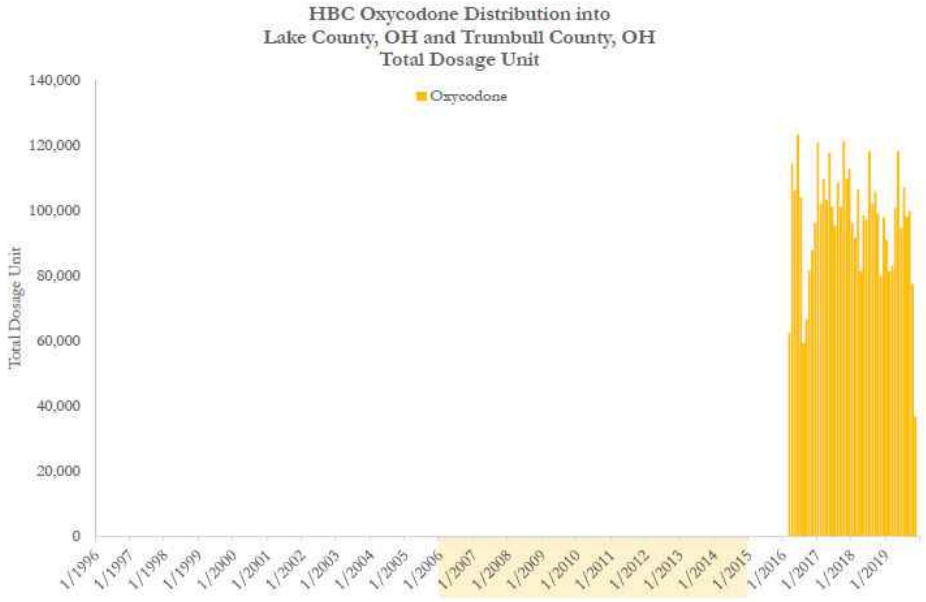
5. Opinions Related to Giant Eagle's Distribution through HBC Service Company and GERX:

a. *Giant Eagle failed to **maintain effective control** against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].*

The graphs below demonstrate a clear escalation of prescription oxycodone and hydrocodone by HBC/Giant Eagle into Lake and Trumbull Counties.[655]

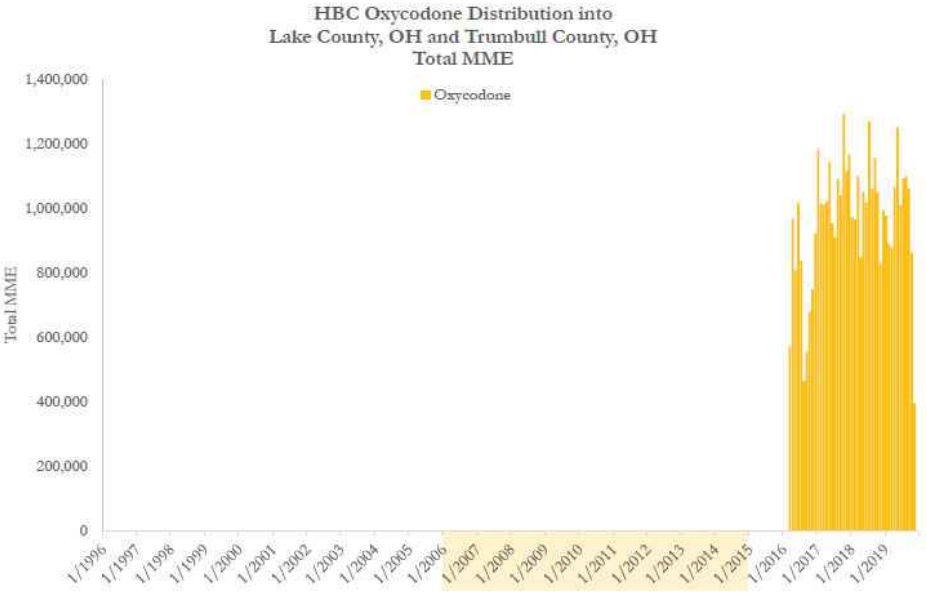
[655] Report of McCann, Appendix 9.

Region: Lake County, OH and Trumbull County, OH
Time: 11/2009 - 11/2019
Seller: HBC
Buyer: All Buyers
Drug: Oxycodone



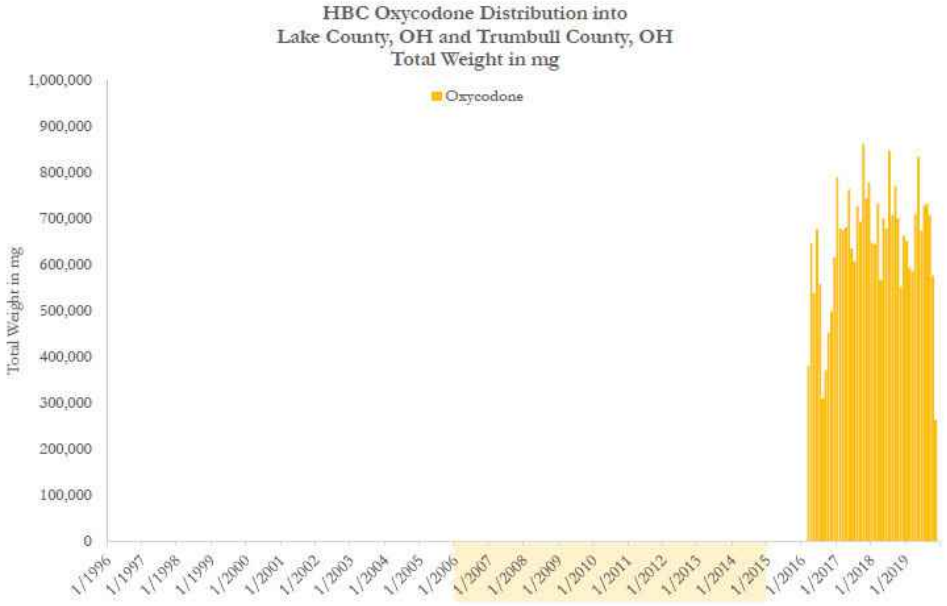
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 11/2009 - 11/2019
Seller: HBC
Buyer: All Buyers
Drug: Oxycodone



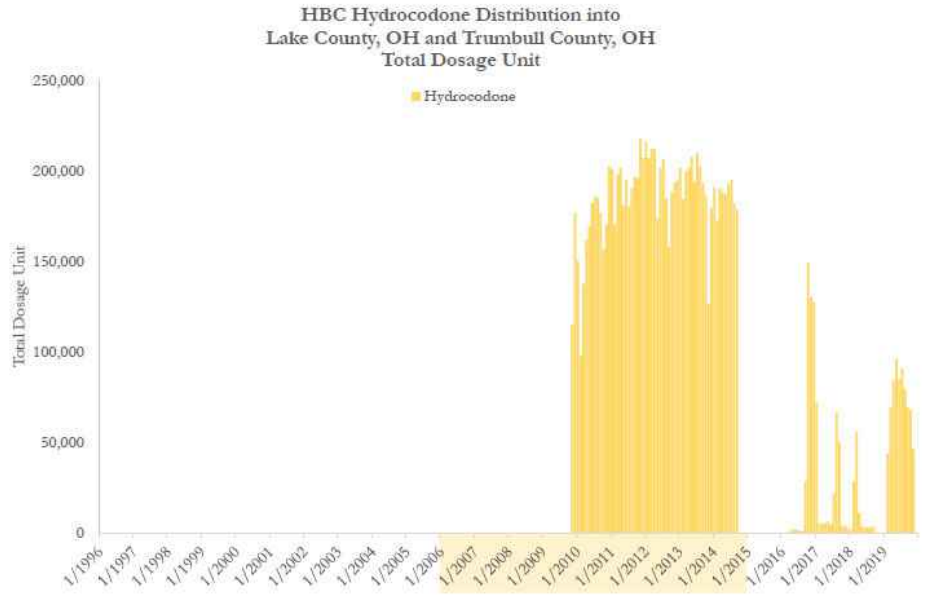
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 11/2009 - 11/2019
Seller: HBC
Buyer: All Buyers
Drug: Oxycodone



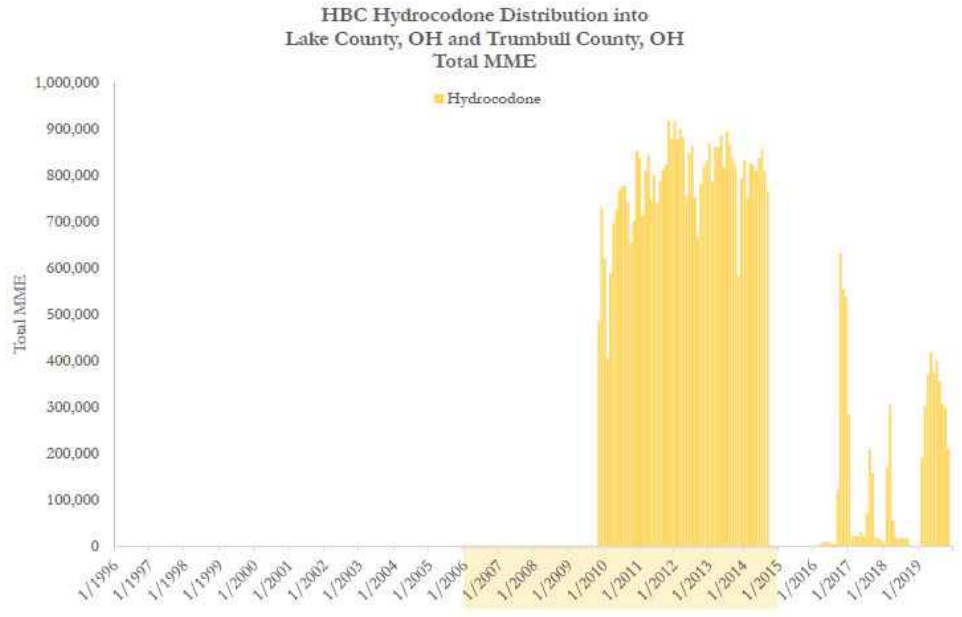
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 11/2009 - 11/2019
Seller: HBC
Buyer: All Buyers
Drug: Hydrocodone



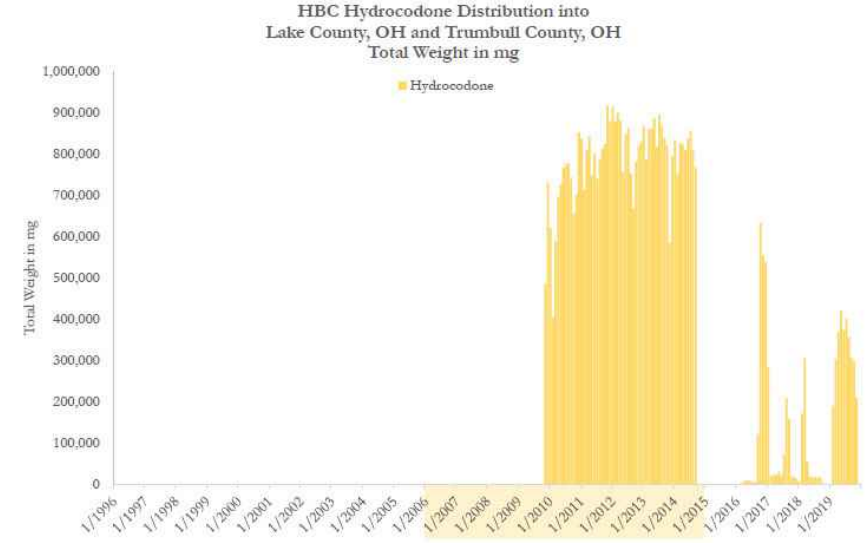
Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 11/2009 - 11/2019
Seller: HBC
Buyer: All Buyers
Drug: Hydrocodone



Data Source: Defendant Transactional Data

Region: Lake County, OH and Trumbull County, OH
Time: 11/2009 - 11/2019
Seller: HBC
Buyer: All Buyers
Drug: Hydrocodone



Data Source: Defendant Transactional Data

In my opinion the massive increase in prescription opioids without sufficient due diligence documented is indicative of a failure to maintain effective control.

Despite distributing opiates into CT3 jurisdictions for more than ten years, Giant Eagle never reported *any* suspicious orders arising out of the CT3 jurisdictions.[656] Outside of CT3, Giant Eagle only notified the DEA of a suspicious order twice, as discussed more fully below. For the majority of the time Giant Eagle distributed opioids to its own pharmacies, it failed to implement a system to hold or blocked order that exceeded thresholds, and only flagged orders post-shipment.

b. Giant Eagle failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the ***security requirement*** set forth in 21 C.F.R. § 1301.74(b).

1) **Giant Eagle's Self-Distribution of Opioids Prior to Implementation of Written SOMS Policy (November 2009-August 1, 2014):**

Giant Eagle shipped prescription opioids into CT3 jurisdictions from its HBC distribution center without a written SOM policy for nearly five (5) years and without a threshold system for four (4) years, which is the majority of the time Giant Eagle shipped opioids through HBC. Between November 2009 and October 14, 2013, HBC did not utilize a threshold to monitor its customers orders. Giant Eagle did not have a written SOM policy until August 1, 2014.[657]

Giant Eagle claims that its SOMS from 2009 until 8/1/14 consisted of inventory audits, the warehouse "pickers," the warehouse superintendent, and the HBC DC procurement team who bought the drugs for the warehouse to distribute "knowing what to look for."[658] There was no computerized system in place that might assist in recognizing suspicious orders until, at the very earliest, 2013. Neither the warehouse superintended nor the procurement team received training on SOMs, nor was there any written instructions or guidances as to what they should be looking for in performing SOM related duties.[659] Giant Eagle's distribution 30b6 witness could point to no data, reports, information, or anything else that these individuals had available to them to detect suspicious orders.[660]

2) **Giant Eagle's Threshold System**

Giant Eagle first established thresholds to monitor its distribution of controlled substances to its pharamacies in mid-October 2013 when it began creating daily threshold reports.[661] HBC's thresholds were set at 3 times the rolling 12 month company average for a given chemical/ingredient group.[662] Because of this methodology, some stores could be flagged on the

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[656] *See* Giant Eagle's First Amended Responses to Plaintiffs First Combined Track 3 Interrogatories at p. 24.

[657] HBC_MDL00133445.

[658] Tsipakis 12/13/18 Depo., 94:3-106:17; 109:6-110:1.

[659] Tsipakis 12/13/18 Depo., 103:17-104:2; 109:6-116:2.

[660] Tsipakis 12/13/18 Depo., 94:3-116:2.

[661] Tsipakis 12/13/18 Depo., 117:5-17; 130:4-19; HBC_MDL00002242 - HBC_MDL00003463; HBC_MDL00008498; HBC_MDL00008726.

[662] Tsipakis 12/13/18 Depo., 117:18-118:119:17.

report every day while others were not likely to show on the reports at all. Giant Eagle admitted that using a company-wide average for the threshold could lead to a lot of false positives and false negatives.[663] Giant Eagle further admitted that the threshold report tracked shipped quantities, not ordered quantities, thus no pre-shipping due diligence occurred in relationship to the report.[664] HBC's threshold system was fatally flawed because it was a post-shipment report, was based on a chain-wide threshold, did not stop orders from shipping, and was systemically ignored.

Giant Eagle continued to use a chain-wide threshold as part of its SOM system – meaning each store was measured according to a chain wide averages regardless of a particular pharmacy's ordering history, frequency, or the population that pharmacy served, until 2017 when the thresholds began to be based on individual store profiles.[665]

The threshold system did not block orders, but flagged orders that were "in process of shipping or having been shipped."[666] All orders listed on the threshold report were shipped – none have ever been recalled.[667] During the majority of the time Giant Eagle self distributed to its pharmacies, it did not have any policy in place to prevent flagged orders from being shipped until they were cleared.[668] Giant Eagle did not develop a system to stop an order if it hit a threshold until January of 2017.[669]

Giant Eagle's threshold reports often flagged a large number of pharmacies as having shipped amounts over the 3 times or triple threshold. While I have not seen evidence to support this, Giant Eagle claims that it "cleared" each flag from every store off of these threshold reports.[670] Giant Eagle's own documents highlight the ineffective and inadequate programs in place. Some reports have 183 threshold violations for a single month.[671] At least one Giant Eagle pharmacy appears to have exceeded the triple threshold limits for HCPs on the threshold reports between 2009 and 2014 when Giant Eagle distributed HCPs through HBC.[672] For example, in October 2016, 11 of 16 pharmacies in Lake and Trumbull Counties are flagged as exceeding the triple thresholds.[673] Store 1405, which is a pharmacy in the City of Niles in Trumbull County, had

[663] Tsipakis 12/13/18 Depo., 165:14-166:4; 247:11-248:3.

[664] Tsipakis 12/13/18 Depo., 165:14–168:2.

[665] Tsipakis 12/13/18 Depo., 135:8-136:20; 167:169:16.

[666] Tsipakis 12/13/18 Depo., 135:8-136:20; 174:23.

[667] Tsipakis 12/13/18 Depo., 176:10-14; 177:7-22.

[668] Tsipakis 12/13/18 Depo., 173:10-14.

[669] Tsipakis 12/13/18 Depo., 215:16-21.

[670] Tsipakis 12/13/18 Depo., 163:4–18.

[671] HBC_MDL00003126.

[672] HBC_MDL00002348, HBC_MDL00002646, HBC_MDL00002700.

[673] HBC_MDL00003126.

the chain-wide threshold of 4895 for a generic hydrocodone.[674] This threshold is already 3 times the monthly average of the rolling 12 month average nationwide. Despite the already significantly inflated threshold of 4895 generic hydro, Golden Eagle shipped 21,500 in October 2016.[675] I did not see any documentary evidence to support an investigation into these substantial deviations from the triple the monthly average thresholds.

3) **Giant Eagle's Written SOMS Policies implemented in 2014, 2015, and 2017**

Giant Eagle admitted it did not have any written suspicious order monitoring policy in effect until August 1, 2014.[676] Giant Eagle's first written SOM policy was adopted on August 1, 2014 and consisted of four short bullet points which were part of a larger distribution policy.[677] The policy does not identify how HBC's suspicious order monitoring system operated, but rather, outlines the process for reporting suspicious product orders. The policy does not elaborate on how to identify a suspicious order, nor does HBC's warehouse supervisor recall any specific training on identifying suspicious orders.[678]

This policy relied on Giant Eagle's corporate office to alert Giant Eagle if its pharmacies engaged in suspicious ordering.[679] The policy also directed that Giant Eagle would prepare and communicate any history of suspicious orders to the GE Pharmacy team "as requested," not making such a report a matter of course. The policy then required GE Pharmacy team, not the distribution center, to notify the DEA "with in [sic] the prescribed three day time limit."

In 2016, Giant Eagle prepared a revised SOM Policy for use at GERX DC, which was substantially similar to the 2015 policy.[680] Even after these revisions, Giant Eagle internally assessed that its own "suspicious order monitoring program is 75 to 85 percent of where it needs to be."[681] Neither of these revisionrs resulted in Giant Eagle reporting any suspicious orders of opioids from CT3 to the DEA.

In February and March of 2017, Giant Eagle implemented two further revised policies: the Order Monitoring System Policy (February 2, 2017)[682] and the Giant Eagle Suspicious Order

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[674] *Id.*

[675] *Id.*

[676] Tsipakis 12/13/18 Depo., 94:3-9.

[677] HBC_MDL00133445.

[678] Rogos Depo., 71:10-72:2; 77:23-78:13.

[679] *Id.*

[680] HBC_MDL00004386.

[681] Tsipakis 12/13/18 Depo., 229:12-230:12.

[682] HBC_MDL00045916.

Monitoring (March 26, 2017).[683] Through these policies, Giant Eagle added the use of algorithms to identify suspicious orders to be investigated before being released for distribution. The OMS algorithm also generated threshold limits, and blocked orders in excess of thresholds, for stores based on pharmacy location, chemical type, Generic Product Indicator (GPI), National Drug Code (NDC), and ordering patterns. The OMS also added four potential levels of review for blocked orders to be investigated prior to being either released to the Giant Eagle pharmacy or reported as suspicious. Investigations would review greater store details such as mapping prescription providers, mapping patients, analyzing payment type, and historic physical inventory of the stores. This version of the policy also adds an investigator level of review for suspicious orders that may involve personnel interviews and "store covert investigation." The results of the investigation determine whether to notify the DEA.[684] Giant Eagle testified that the information used to create the 2017 SOM system was always available at Giant Eagle, though not incorporated into the SOM policies.[685] Again, none of these revisions resulted in Giant Eagle reporting any suspicious orders of opioids from CT3 to the DEA.

6. **Due Diligence Conducted:**

Based on Giant Eagle's deposition designations, I have been provided only minimal evidence of due diligence compared to the number of shipments exceeding the set threshold and certainly not anything to suggest that every individual shipment in excess of the threshold was investigated as a normal course of business. The emails and other documents reviewed indicate that only a handful of investigations occurred at periodic times and that such investigations were insufficient to meet Giant Eagle's obligations under the CSA.[686] In fact Giant Eagle admitted that it could find no documentation of investigations into suspicious orders from 2009 through 2014.[687] For example, Giant Eagle admits that due diligence investigations would only occur once for a store for the month even if the store continued to order controlled substances above the threshold amounts even where the threshold was triple the nationwide monthly average.[688] Giant Eagle allowed pharmacies which exceeded the triple threshold to continue to exceed the threshold with subsequent orders without any additional scrutiny until the end of the month.

Giant Eagle claims that it "investigated and cleared" every store that was flagged by its daily threshold reports.[689] However, Giant Eagle also admits that it did not develop a system for entering investigative notes and information regarding flagged orders until 2017.[690] Further, at

[683] HBC_MDL00051908; HBC_MDL00043414. *See also* HBC_MDL00010092.

[684] Tsipakis 12/13/18 Depo. 82:1-93:8; Ex. 12 at HBC_MDL00045917.

[685] Tsipakis 12/13/18 Depo., 88:24-90:11.

[686] HBC_MDL00039223 (Jan. 10, 2014); HBC_MDL00058099; HBC_MDL00090010 (July 8, 2014).

[687] Tsipakis 12/13/18 Depo., 191:12-18 and 196: 4-12.

[688] Millward Depo., 276:3–15.

[689] Tsipakis 12/13/18 Depo. . 163:4–10; 177:16-178:6 and Millward 202:21-203:14.

[690]Tsipakis 12/13/18 Depo., 162:9.

least through 2017, orders were not even flagged for analysis on the threshold report until after they were shipped.[691]

There is limited evidence of isolated incidents of due diligence within the documents Giant Eagle produced, however, only one of these incidents includes an investigation of orders for HCPs and the store in question is not within Lake or Trumbull County.[692] Giant Eagle witnesses have acknowledged that they have no recollection of specific investigations, that they had no systematic process in place to investigate flagged orders, and that they have no log or report to document that an investigation occurred for each flagged order.[693] Furthermore, the emails and other documents produced indicate only a handful of investigations occurred at periodic times and that such investigations were cursory at best.[694] Giant Eagle testified that, in its entire history, it "only had very few suspicious orders."[695]

7. **Reporting Requirement**:

Giant Eagle never reported any suspicious orders arising out of CT3. From 2009-2018, Giant Eagle only reported two suspicious orders to the DEA in total.[696] Giant Eagle testified that there was never a "suspicious order" of HCPs in the HBC/Giant Eagle system between 2009 and 2014 despite the fact that millions of HCPs were distributed to pharmacies in the relevant jurisdictions during this entire timeframe.[697]

In December 2013, Giant Eagle reported its first of two reported suspicious orders to the DEA.[698] That suspicious order was for buprenorphine, which is an opioid, but not relevant to the current litigation. Giant Eagle submitted one additional suspicious order (also buprenorphine) in January 2016, after opening the GERX DC.[699]

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[691] Tsipakis 12/13/18 Depo. 215:6-21.

[692] HBC_MDL00002303, HBC_MDL00002309, HBC_MDL00134729.

[693] Tsipakis 12/13/18 Depo. 114:20–116:17; Mollica Depo.48:9-49:15, 237:4-13; and Millward Depo. 186:21-187:6.

[694] *See* e.g. HBC_MDL00039223, HBC_MDL00058099, HBC_MDL00090010.

[695] Tsipakis 12/13/18 Depo. 174:24-176:14.

[696] Tsipakis 12/13/18 Depo. 198:20-199:14.

[697] Tsipakis 12/13/18 Depo. 198:20-199:14.

[698] HBC_MDL00132815.

[699] HBC_MDL00057971.

8. **Shipping Requirement:**

Despite representing to its upstream vendors that it screened and stopped suspicious shipments from shipping, Giant Eagle did not have the ability to automatically stop orders from shipping which exceeded its set threshold during the period that Giant Eagle shipped controlled substances.[700]

Giant Eagle also did not manually stop suspicious orders from shipping which had been flagged by its threshold report. Giant Eagle admitted that its threshold reports tracked already shipped, not ordered materials,[701] which did not leave an adequate window or process to identify, stop and investigate unusual orders once it became aware of them.

After Giant Eagle stopped shipping prescription opioids through HBC, it had the opportunity for GERX DC to utilize a third-party system to stop over-threshold orders from shipping. Giant Eagle's Senior Pharmacy Director Adam Zakin declined, claiming it was not worth the expense because the only thing the new system would do was "stop the orders physically if there were a threshold."[702]

By:

James Rafalski
April 16, 2021

[700] HBC_MDL00029196; ENDO_HSGAC_0007618 at -0007621; HBC_MDL00169476; Tsipakis 12/13/18 Depo., 213:8–10, 255:24–256:23; HBC_MDL00028498.

[701] Tsipakis 12/13/18 Depo., 141:3–11.

[702] HBC_MDL00028498, email, March 29, 2016.

April 16, 2021 Expert Report of James Rafalski

Schedule I

Anda_Opioids_MDL_0000476052
ABDCMDL00143304
ABDCMDL00170319
ABDCMDL00269685
Acquired_Actavis_00441354 at 441355
CAH_MDL_PRIORPROD_DEA_12_00011059
CAH_MDL_PRIORPROD_DEA07_00092296
CAH_MDL_PRIORPROD_DEA07_00837645
CAH_MDL_PRIORPROD_DEA07_01185382
CAH_MDL_PRIORPROD_DEA07_01198690
CAH_MDL_PRIORPROD_DEA12_00000825
CAH_MDL_PRIORPROD_DEA12_00000826
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CAH_MDL_PRIORPROD_DEA12_00014479
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CAH_MDL2804_01465723
CAH_MDL2804_01483146
CAH_MDL2804_01563592
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CAH_MDL2804_02203353
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CVS MDLT1-000028391-000028393
CVS-BAL-000013729
CVS-FLAG-000021256

CVS-FLAG-000021435
CVS-FLAG-000030655
CVS-FLAG-000031768
CVS-FLAG-000033005
CVS-FLAG-000036052
CVS-FLAG-000039494
CVS-IQVIA-000000120-125
CVS-IQVIA-000001301-1310
CVS-IQVIA-000001835-1872
CVS-IQVIA-000001870
CVS-MD LT1-00034175-34176
CVS-MDLT-000110442-000111185
CVS-MDLT1-000 101181
CVS-MDLT1-000 101385
CVS-MDLT1-000000001
CVS-MDLT1-000000299
CVS-MDLT1-000000299–00000303
CVS-MDLT1-000000409
CVS-MDLT1-0000010201–000010212
CVS-MDLT1-000001022
CVS-MDLT1-000001074
CVS-MDLT1-0000020426–20428
CVS-MDLT1-000003021
CVS-MDLT1-000003028
CVS-MDLT1-0000030545–000030548
CVS-MDLT1-000003177
CVS-MDLT1-000008014
CVS-MDLT1-000008413
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WMT_NV_000001159
WMT_NV_000001290
WMT_NV_000001325

WMT_NV_000001329
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WMT_NV_000001472
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WMT_NV_000001488
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WMT_NV_000001534
WMT_NV_000001536
WMT_NV_000001538
WMT_PA_0000000050
WMT_PA_0000000151
WMT_PA_0000000398
WMT_PA_000000226
WMT_PA_000000226
WMT_PA_000000227
WMT_PA_000000233
WMT_PA_000000262
WMT_PA_000000268
WMT_PA_000000279
1/10/219 Deposition of Roxanne Reed and Exhibits
1/16/2019 Deposition of Kristy Spruell and Exhibits
1/22/2019 Deposition of Susan Hiland and Exhibits (30(b)(6))
1/23/2019 Deposition of Susan Hiland and Exhibits (Fact)
11/15/2018 Deposition of Jeff Abernathy and Exhibts
11/16/2018 Deposition of Chad Ducote and Exhibits
12/12/2018 Deposition of Miranda Johnson and Exhibits
2/11/2019 Deposition of Ramona Sullins and Exhibits
2018.07.05. Rite Aid's Responses to Plaintiffs' Interrogatories
2018.07.05. Rite Aid's Responses to Plaintiffs' RFPs
2018.07.26 HBC Service Company's Responses and Objections to First Notice of 30(B)(6) deposition (07.26.2018)
2018.07.26 HBC Service Company's Responses and Objections to Second Notice of Deposition Pursuant to 30(b)(6)
2018.09.21. Rite Aid's Amended Responses to Plaintiffs' Interrogatories
2018.09.25. Rite Aid's Supplemental Responses to Plaintiffs' RFPs
2018.11.09. Rite Aid's Written Responses to Second 30(b)(6) (Topics 1 and 2)
2018.11.30. Rite Aid's Responses to Combined Discovery Requests
2018.12.29 HBC Service Company's First Amended Response to Plaintiffs' (First) Set of RFPs (12.29.2018)
2019.01.07. Rite Aid's Written Responses to 30(b)(6) Topics
2019.01.25. Rite Aid's Second Supplemental Responses to Interrogatories

2019.02.13 HBC Service Company's Second Amended Responses to Plaintiffs' (First) Combined Discovery Requests (02.13.2019)
2019.03.04 HBC Service Company's Written 30b6 Response to Plaintiffs' 2d Notice of Depo (03.04.2019)
2019.03.04. Rite Aid's Third Supplemental Responses to Interrogatories
2019.03.29 HBC Service Company's Second Supplemental Response to Plaintiffs' (First) set of Interrogatories (03.29.2019)
2019.12.20. Rite Aid's Responses to CT1B 1st Combined Disc. Requests
2019.12.31. Rite Aid's Responses to CT1B Initial Disclosures
2020.07.13. Rite Aid's Responses to Plaintiffs' First Combined Interrogatories
2020.07.13. Rite Aid's Responses to Plaintiffs' First Combined RFPs
2020.07.27 HBC Responses and Obj to Pls' Track 3 RPD Nos. 1-3, 5, 9, 11-18, 20-23, 25, 27-29, and 31-33
2020.07.27 HBC Responses and Objections to Pls' Track 3 Interrogatories 4, 5, 7, 9-13 (A1489004)
2020.07.27. Rite Aid's Supplemental Responses to First Combined Interrogatories
2020.07.27. Rite Aid's Supplemental Responses to First Combined RFPs
2020.08.12 GE + HBC First Amended Responses and Objections to Pls' (First) Combined Track 3 RFPs (08.12.2020)
2020.08.12 GE + HBC First Amended Responses and Objections to P's (First) Combined Track 3 Interrogatories (08.12.2020)
2020.08.12 HBC Amended Responses and Objections to Pls' Track 3 Interrogatories (A1494299) (002)
2021.01.22 GE + HBC Responses and Objections to Plaintiffs' (Second) Combined Track 3 Interrogatories (01.22.2021)
2021.02.22 GE + HBC Answers and Objections to 30(b)(6) Topics 3-9 in Plaintiffs' Notice of Deposition (02.22.2021)
2021.03.15 GE + HBC Answers and Objections to 30(b)(6) Topics 8, 9, 11, and 12 (03.15.2021)
20210122 CT3 Rite Aid Objs & Resps to 2nd Set of ROGs
All discovery responses served by Defendants included in my report.
Amended Response to Interrogatory No. 3 at CVS'S AMENDED OBJECTIONSAND RESPONSES TO INTERROGATORIES NOS. 3, 4, 8, 9, 10 AND 11 OF PLAINTIFFS' (FIRST) COMBINED TRACK THREE INTERROGATORIES TO CHAIN PHARMACY DEFENDANTS.
April 17-18, 2019 and May 17, 2019 Deposition of Thomas Prevoznik (Vol. I, II, & III) and Exhibits
April 26, 2019 and May 15, 2019 Deposition Transcript of Joseph Rannazzisi and Exhibits
CVS'S WRITTEN RESPONSES TO TOPICS 8, 9, 12, 13 AND 14 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6), Response No. 14.
December 13, 2018 Deposition of James Tsipakis (30(b)(6)) and Exhibits
December 14, 2018 Deposition of Stephan Bamberg and Exhibits
December 16, 2018 Deposition of Edward Bratton and Exhibits
December 18, 2018 Deposition of EugeneTommasi and Exhibits
December 18, 2018 Deposition of Richard Chapman and Exhibits
December 18, 2019 Deposition of Ed Kaleta and Exhibits
December 20, 2018 Deposition of Christopher Belli and Exhibits
December 20, 2018 Deposition of Douglas Peterson and Exhibits
December 20, 2018 Deposition of Joseph Millward and Exhibits

December 20, 2018 Deposition of Mike Bleser and Exhibits
December 21, 2018 Deposition of Rex Swords and Exhibits
December 31, 2019 WALGREENS' RESPONSE TO PLAINTIFFS' "INITIAL DISCLOSURES" REQUESTS
December 6, 2018 Deposition of Mark Nicastro and Exhibits
December 6, 2018 Mark NiCastro Deposition and Exhibits
Deposition Transcripts of Craig McCann and Exhibits (MDL 2804 CT1 & CT2, and NY Opioid Litigation)
February 1, 2019 Deposition of Deb Bish and Exhibits
February 15, 2021 WALGREEN CO., WALGREEN EASTERN CO., AND WALGREENS BOOTS ALLIANCE, INC.'S WRITTEN RESPONSES TO CERTAIN OF PLAINTIFFS' RULE 30(b)(6) TOPICS
February 19, 2019 Deposition of Randy Heiser and Exhibits
February 19, 2019 Deposition of Phillip Raub and Exhibits
February 19, 2019 Deposition of Wayne Bancroft and Exhibits
February 19, 2019 WALGREEN CO. AND WALGREEN EASTERN CO.'S SECOND SUPPLEMENTAL RESPONSES TO PLAINTIFFS' "(FIRST) COMBINED DISCOVERY REQUESTS"
February 21, 2020 WALGREENS' SUPPLEMENTAL RESPONSES TO PLAINTIFFS' (FIRST) COMBINED DISCOVERY REQUESTS TO DISPENSERS
February 22, 2019 Deposition of Matthew Rogos and Exhibits
February 26, 2021 WALGREEN CO., WALGREEN EASTERN CO., AND WALGREENS BOOTS ALLIANCE'S WRITTEN RESPONSES TO CERTAIN OF PLAINTIFFS' RULE 30(b)(6) TOPICS
Giant Eagle's First Amended Responses to Plaintiffs First Combined Track 3 Interrogatories
January 1, 2020 Walmart Inc.'s Objections and Respones to Plaintiffs' "Initial Disclosures" Requests
January 1, 2020 Walmart Inc.'s Objections and Respones to Plaintiffs' First Combined Disocvery Requests to Dispensers
January 10, 2019 Deposition of Shauna Helfrich and Exhibits
January 11, 2019 Deposition of Gary Millikan and Exhibits
January 14, 2019 Deposition of Andrea Bucher and Exhibits
January 14, 2019 Deposition of Ed Lanzetti and Exhibits
January 14, 2019 Deposition of Tomson George and Exhibits
January 15, 2019 Deposition of Denny Murray and Exhibits
January 15, 2019 Deposition of Keith Frost and Exhibits
January 16, 2019 Deposition of George Chunderlik and Exhibits
January 16, 2019 Deposition of Kevin Mitchell and Exhibits
January 17, 2019 Craig Deposition of Schiavo and Exhibits
January 17, 2019 Deposition of Aaron Burtner and Exhibits
January 17, 2019 Deposition of Barbara Martin and Exhibits
January 17, 2019 Deposition of Christopher Domzalski and Exhibits
January 17, 2019 WALGREEN CO. AND WALGREEN EASTERN CO.'S OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) TOPIC 1(O) AND SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) TOPICS 2 (A)-(J), 9, 10, 11, 13, 14 AND 15

January 21, 2019 Deposition of Sean Barnes and Exhibits
January 22, 2019 Deposition of Andrew Palmer and Exhibits
January 22, 2019 Deposition of Fred Bencivego and Exhibits
January 22, 2019 Deposition of Walter Wayne Durr and Exhibits
January 22, 2020 Walmart's Objections and Responses To Plaintiffs' (Second) Combined Track Three Interrogatories to Chain Pharmacy Defendants.
January 22, 2021 CT3 Walmart Objs & Resps to 2nd Set of ROGs
January 23, 2019 Deposition of Henry Mortelliti and Exhibits
January 23, 2019 Deposition of Tasha Polster and Exhibits
January 23, 2019 Deposition of Terence Dugger and Exhibits
January 23, 2020 WALGREENS' SUPPLEMENTAL RESPONSES AND OBJECTIONS TO PLAINTIFFS' (FIRST) (MODIFIED) (COMBINED) TRACK THREE INTERROGATORIES
January 24, 2019 Deposition of Ellen Wilson and Exhibits
January 24, 2019 Deposition of Jen Diebert and Exhibits
January 24, 2019 Deposition of Kelly Baker and Exhibits
January 24, 2019 Deposition of Larry Ringgold and Exhibits
January 24, 2019 Deposition of Marian Wood and Exhibits
January 24, 2019 Deposition of Pam Hinkle and Exhibits
January 25, 2019 Deposition of Chris Dymon and Exhibits
January 25, 2019 Deposition of Robert McClune and Exhibits
January 25, 2019 Deposition of Sherri Hinkle
January 30, 2019 Deposition of Janet Hart (Fact) and Exhibits
January 31, 2019 Deposition of Janet Hart (30(b)) and Exhibits
January 4, 2019 Deposition of Anthony Mollica and Exhibits
January 4, 2019 Deposition of Debra Chase and Exhibits
January 7, 2019 Walmart Inc.'s Written Responses to Plaintiffs' Rule 30(b)(6) Notices to Walmart
January 8, 2019 Deposition of Gregory Carlson and Exhibits
January 9, 2019 Deposition of Sophia Novack and Exhibits
January 9, 2019 Walmart Inc.'s Second Amended And Supplemental Objections and Respones to Plaintiffs' First Set of Interrogatories to Wal-Mart Inc.
July 11-12, 2019 Deposition Transcript of Michael Mapes and Exhibits
July 13, 2020 CT3 CVS Health Objs to RFPs Nos 4, 6, 7, 8, 10, 19, 24, 26, 30
July 13, 2020 CT3 CVS Health Objs to ROGs Nos 1, 2, 3, 6, 8
July 13, 2020 CT3 CVS Objs & Resps to RFPs Nos 4, 6, 7, 8, 10, 19, 24, 26, 30
July 13, 2020 CT3 CVS Objs & Resps to ROGs Nos 1, 2, 3, 6, 8
July 13, 2020 CT3 Walmart Resps & Objs to Plts 1st Combined RFPs to Pharma Defs
July 13, 2020 CT3 Walmart Resps & Objs to Plts 1st Combined ROGs to Pharma Defs
July 13, 2020 WALGREENS' RESPONSES AND OBJECTIONS TO PLAINTIFFS' (FIRST) (MODIFIED) (COMBINED) TRACK THREE INTERROGATORIES
July 13, 2020, Walgreens' Responses and Objections to Plaintiffs' (First) (Modified) (Combined) Track Three Interrogatories.

July 24, 2020 Walmart's Objections and Responses To Plaintiffs' (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants
July 24, 2020 Walmart's Objections and Responses To Plaintiffs' (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants
July 24, 2020 Walmart's Objections and Responses To Plaintiffs' Requests for Production of Documents to Walmart (First) Combined Track Three Interrogatories to Chain Pharmacy Defendants
July 27, 2020 CT3 CVS Health Obj to Plts 1st Combined RFPs
July 27, 2020 CT3 CVS Health Obj to Plts 1st Combined ROGs
July 27, 2020 CT3 CVS Resps & Objs to Plts 1st Combined RFPs
July 27, 2020 CT3 CVS Resps & Objs to Plts 1st Combined ROGs
July 27, 2020 CT3 Walmart Resps & Objs to Plts 1st Combined RFPs
July 27, 2020 CT3 Walmart Resps & Objs to Plts 1st Combined ROGs
July 29, 2020 Deposition of DonaldTush and Exhibits
July 7, 2020 CT3 Walmart Objs & Resps to RFPs
July 7, 2020 Walmart's Objections and Responses To Plaintiffs' Requests for Production of Documents to Walmart
June 20, 2018 Walmart's Objections and Responses To Plaintiffs' First Set of Requests for Production to Wal-Mart Inc.
June 20, 2018 Walmart's Objections and Responses To Plaintiffs' First Set of Requests Interrogatories to Wal-Mart Inc.
June 20, 2019 Walmart Inc.'s Fourth Amended And Supplemental Objections and Respones to Plaintiffs' First Set of Interrogatories to Wal-Mart Inc.
June 20, 22019 Walmart's Fourth Amended and Supplemental Interrogatory Res.
June 28, 2019Deposition Transcript of Ronald Buzzeo and Exhibits
March 1, 2021 Deposition of Tasha Polster (30(b)) and Exhibits
March 10, 2021 Deposition of Scott Jacobson and Exhibits
March 12, 2021 Deposition of Kirsten Gosnik and Exhibits
March 15, 2021 Deposition of Lewis Colosimo and Exhibits
March 16, 2021 Deposition of Janet Hart and Exhibits
March 2, 2021 Deposition of Papatya Tankut and Exhibits
March 31, 2021 Deposition of Justin Joseph and Exhibits
March 4, 2019 WALGREEN CO. AND WALGREEN EASTERN CO.'S SECOND AMENDED OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST SET OF INTERROGATORIES
March 4, 2019 Walmart Inc.'s Third Amended And Supplemental Objections and Respones to Plaintiffs' First Set A107:A186of Interrogatories to Wal-Mart Inc.
March 4, 2021 Deposition of Thomas Davis and Exhibits
March 5, 2019 Errata to Ed Bratton 30(b)(6) Deposition
March 5, 2021 Deposition of Joseph Grimes and Exhibits
March 5, 2021 Deposition of Rick Shaheen and Exhibits
March 5, 2021 Deposition of Steve Kneller and Exhibits
March 5, 2021 WALGREENS' THIRD SUPPLEMENTAL RESPONSES AND OBJECTIONS TO PLAINTIFFS' (FIRST) (MODIFIED) (COMBINED) TRACK THREE INTERROGATORIES
March 8, 2021 Deposition of George Chunderlik (30(b)(6)) and Exhibits

May 10, 2019 Deposition Transcript of Patrick Kelly and Exhibits
November 13, 2020 Deposition of Claire Brennan
November 13, 2020 Deposition of DEA 30(b)(6) designee Claire Brennan and Exhibits
November 15, 2018 Deposition of Patricia Daugherty and Exhibits
November 20, 2018 Deposition of Mark Vernazza (30(b)) and Exhibits
November 28, 2018 Walmart's Am and Sup Obj to Pltfs' 1st RFP
November 29, 2018 Deposition of Amy Propatier and Exhibits
November 30, 2018 Walmart Inc.'s Responses to PLTFs 1st Combined Disc Requests
November 30, 2018 Walmart's Objections and Responses To Plaintiffs' (First) Combined Discovery Requests to Retail Pharmacy Defendants
November 8, 2018 Deposition of Steve Mills and Exhibits
October 16, 2018 Deposition of Eric Stahmann and Exhibits
October 16, 2020 CT3 CVS Amd Objs & Resps to RFP Nos 4, 6-8, 19, 26, 30
October 16, 2020 CT3 CVS Amd Objs & Resps to ROG Nos 1-3, 8, 10-11
October 30, 2020 CT3 CVS Amd Objs & Resps to ROG Nos 10-11
Rite Aid Responses to Combined Interrogatory 2 served 11/30/18.
September 21, 2018 Walmart Amd & Suppl Obj & Resp to Plf 1st Set of RFPs
September 21, 2018 Walmart Amd & Suppl Obj & Resp to Plf 1st Set of ROGs
September 21, 2018 Walmart's Amended and Supplemental Objections and Responses To Plaintiffs' First Set of Interrogatories to Wal-Mart Inc.
September 21, 2018 Walmart's Amended and Supplemental Objections and Responses To Plaintiffs' First Set of Requests for Production to Wal-Mart Inc.
Walmart Inc.'s Written Repsonse to First 30(b)(6) Ntoice Topic (k)(1) and Second Notice Topic 18 identifying the Bates number and effective date of the initial thresholds used as part o fthe Reddwerks enhancements. (Email from T. Fumerton et al to M. Innes et al dated January 21. 2019)
WMT Responses to Combined Discovery served 11/30/18
"Akron Doctor Sentenced to 10 Years in Prison For Illegally Prescribing Painkillers, Even After Patients Died," U.S. Dep't of Justice Press Release (Feb. 13, 2015) https://www.justice.gov/usao-ndoh/pr/akron-doctor-sentenced-10-years-prison-illegally-prescribing-painkillers-even-after
1970 U.S.C.C.A.N. 4566 (Sept. 10, 1970)
2017 Settlement Agreement and Release between U.S. DOJ and DEA and McKesson Corporation, available at https://www.justice.gov/opa/press-release/file/928471/download
21 CFR §§ 1300-1321
21 USC §§ 801-971
69 FR 51104-02
Administrative Memorandum of Agreement between DEA and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, dated July 7, 2017. Available at https://www.justice.gov/usao-edmi/press-release/file/986026/download
Administrative Memorandum of Agreement between DEA and The Harvard Drug Group, LLC dated March 28, 2011. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Harvard%20Drug%20Group%20-%202011.pdf
AmerisourceBergen New Release – June 22, 2007 – "AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of its Orlando Distribution Center's Suspended License to Distribute

Controlled Substances http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its
ARCOS 2 – Report 7, Summary of Retail Pharmacies, Years 2000 to 2014 posted on DEA website at deadiversion.usdoj.gov
ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, ARCOS Defined (Version 1.0 August 1997).
Article by ASHP titled, "DEA Targets Rogue Internet Pharmacies Drug Sources," by Cheryl A. Thompson, https://www.ashp.org/news/2007/05/16/dea_targets_rogue_internet_pharmacies__drug_sources
Associated Press, "Walgreens to pay $200k, change opioid procedures," The Washington Times, January 19, 2017, available at https://www.washingtontimes.com/news/2017/jan/19/walgreens-to-pay-200k-change-opioid-procedures/
Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, Masters Pharmaceuticals, Inc. v. United States Drug Enforcement Administration, No. 15-1335, U.S. (C.A.D.C.) [Doc. #1607110]
Cardinal Health to Cease Distribution of Controlled Substances from Florida facility https://cardinalhealth.mediaroom.com/newsrelease.com/newsreleasearchive?item=122500
Cardinal Health, Press Release, Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility, November 29, 2007, available at (Source: https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx
Cardinal Health, Press Release, Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility, November 29, 2007, available at (Source: https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx
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Consent Order, United States of America v. Kinray, LLC, (Case 1:16-Cv-9767-RA) https://www.justice.gov/usao-sdny/press-release/file/920806/download
https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf
CVS press release announcing Settlement found at https://cvshealth.com/newsroom/press-releases/cvspharmacy-announces-agreements-us-drug-enforcement-administration-and-us-attorneys-offices.
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DEA press release regarding Dr. Louis J. Cannella, Jr., dated May 19, 2009 https://www.dea.gov/sites/default/files/divisions/det/2009/detroit051909p.html
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DEA suspends a Cardinal substance-control license, https://www.reuters.com/article/cardinal-dea-idUSN2925615720071130
December 23, 2016, Department of Justice, United States Attorney's Office, Southern District of New York, press release titled, "Manhattan U.S. Attorney Announces $10 Million Civil Penalty Recovery Against New York Pharmaceutical Distributor Kinray, Llc. https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-10-million-civil-penalty-recovery-against-new-york
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Department of Justice Files Nationwide Lawsuit Against Walmart Inc. for Controlled Substances Act Violations, Press Release, available at https://www.justice.gov/opa/pr/department-justice-files-nationwide-lawsuit-against-walmart-inc-controlled-substances-act
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February 2009, Vol 99, No. 2, American Journal of Public Health, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/
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H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566 (Sept. 10, 1970)
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June 29, 2017 Memorandum of Agreement between CVS and DEA Eastern District of California
Keysource Med., Inc. v. Holder, No. 1:11-CV-393, 2011 WL 3608097 (S.D. Ohio Aug. 16, 2011
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Paul T. Farrell, Jr.

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FARRELL & FULLER

July 14, 2021

VIA ELECTRONIC MAIL:

EXT-TRACK3DEFENDANTS@GROUPS.JONESDAY.COM

Re: *In re National Prescription Opiate Litig.*, MDL No. 2804, 1:17-md-02804-DAP, Track 3 Cases
Expert Report of James Rafalski – Supplemental Reliance List

Dear Counsel,

Plaintiffs submit the following list of documents to supplement Schedule I of Mr. Rafalski's report served April 16, 2021. Mr. Rafalski reviewed these documents prior to the submission of his report. The documents were inadvertently omitted from his original list of reliance materials.

- WMT_MDL_000286238
- WMT_MDL_000286239
- WMT_MDL_000286240
- WMT_MDL_000416563

Sincerely,

/s/ Michael Fuller

Michael Fuller, Jr.

MJF/ej

cc: Plaintiffs' Counsel
Defendants' Counsel